

## PART I

# Patent protection of biotechnological inventions and the limits of patentability

## I.1 BIOTECHNOLOGY AND PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

The concept of biotechnology refers to a wide range of techniques using living organisms. According to the accepted meaning, biotechnology can be defined as a group of techniques which use living organisms or their parts in order to create or modify products, to improve the characteristics of plants or animals, or to develop microorganisms or organisms destined for specific uses. In other words, biotechnology includes all techniques which use or cause organic changes in biological material, microorganisms or animals, or cause changes in inorganic material, using biological methods.<sup>1</sup>

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<sup>1</sup> According to the Convention on Biological Diversity (Rio de Janeiro, 5 June 1992): 'Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. With regard to the definition of the concept of biotechnology, in doctrine see, among others: A. Kornberg and T.A. Baker, *DNA Replication*, New York: University Science Books, 2005 (2nd edn.), *passim*; L.M. Houdebine, 'Biotecnologie', in *Nouvelle Encyclopedie de Bio-éthique, sous la direction de G. Hottot et J.N. Missa*, Bruxelles: De Boeck, 2001, p. 145 et seq.; J.D. Watson and J. Tooze, *The DNA Story: a documentary history of gene cloning*, San Francisco/Oxford: W.H. Freeman, 1981, *passim*; H.F. Judson, *The Eighth Day of Creation: Makers of the Revolution in Biology*, New York: Cold Spring Harbor, 1996 (25th Anniversary Edition), *passim*; G.S.

A fundamental distinction within the subject exists between traditional biotechnology and so-called innovative or advanced biotechnology. The former consists in biological processes applied by man for centuries for the production of food and drink, cheese and wine, the cultivation of plants and the disposal of waste.<sup>2</sup> Innovative or advanced biotechnology, first developed in the 1970s, is based on the combined use of new biological techniques – such as genetic engineering, the culture of cells *in vitro*, the production of monoclonal antibodies, etc. – applied to various production sectors but brought together with organic material or biological organisms being the final or intermediate products.<sup>3</sup>

Today's biotechnology involves living organisms and their direct genetic modification. Until recently, the modification of living organisms could occur only through gradual selection. The genes which caused the modification of a particular organism could be chosen only from the full group of genes of the species to which the organism belonged.

In 1953 Watson and Crick designed a double helix model of DNA, which allowed for the theorization of the duplication mechanism of genetic material, providing a scientific explanation of the heredity phenomena (previously the subject of Mendel's observations), based fundamentally on subsequent study and intervention in the field of genetics.<sup>4</sup>

In particular, the technological innovations of the 1970s, which facilitated the development of the first recombinant DNA techniques aimed at creating new molecules of DNA through the unification of DNA

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Stent and R. Calendar, *Molecular Genetics: An Introductory Narrative*, San Francisco: CBS Publishers & Distributors, 1986 (2nd edn.), *passim*.

<sup>2</sup> Until the second half of the 1800s, these techniques were limited to the activity of fermentation of microorganisms without the awareness of the related process. It was only after the discoveries of Pasteur that the fermentation processes began to use pure cultures of microorganisms, and as a consequence the industry of fermentation emerged.

<sup>3</sup> In this regard, see E.S. Grace, *Biotechnology Unzipped: Promises & Realities*, Washington DC: Joseph Henry Press, 1997, p. 1 et seq.

<sup>4</sup> Namely science, the branch of biology, which studies the genes, heredity and genetic variability of organisms. For a reconstruction of the developments recalled in the text, see D. Hartl and E. Jones, *Genetics: Analysis of Genes and Genomes*, Burlington (USA): Jones & Bartlett, 2008 (7th edn.), *passim*; R.C. King, W.D. Stansfield and P.K. Mulligan, *A Dictionary of Genetics*, Oxford: Oxford University Press, 2006 (7th edn.), *passim*.

fragments from different species, presented important opportunities for 'genetic engineering', an expression which is used to indicate artificially introduced modifications of the genetic information of a cell through the insertion of other genetic information into it.<sup>5</sup>

These techniques are based on the availability of scientific data regarding the structure of DNA.<sup>6</sup> Given that all living material contains the same type of DNA, the exchange of genetic material between organisms was deemed possible.

In 1973 Cohen and Boyer demonstrated that the DNA of different species could be assembled and inserted into a host organism. The process of assembling DNA is called recombinant DNA technology. Alternatively, the combination of genes of different organisms in order to introduce new properties to the host organism is called genetic engineering. The way in which the procedure is applied to animals is that of modifying genes through the insertion of altered DNA, which causes them to produce substances they normally do not.<sup>7</sup> The organisms whose genetic structure has been modified in this way are called transgenic organisms. These modified microorganisms, plants and animals are used as bioreactors<sup>8</sup> for the production of pharmaceutical substances. Insulin and the human growth hormone are examples of substances which have been produced by microorganisms for many years.

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<sup>5</sup> On the theme see, among others: L. Yount, *Biotechnology and Genetic Engineering*, New York: Facts On File, 2008 (3rd edn.), *passim*; D.S.T. Nicholl, *An Introduction to Genetic Engineering*, Cambridge: Cambridge University Press, 2008 (3rd edn.), *passim*; J.D. Watson, *Recombinant DNA: Genes and Genomes: A Short Course*, San Francisco: W.H. Freeman, 2007, *passim*; S. Smiley, *Genetic Modification: Study Guide (Exploring the Issues)*, Cambridge: Independence Educational Publishers, 2005, *passim*; R.D. Hotchkiss, 'Portents for a Genetic Engineering' (1965) 56 *Journal of Heredity* 197 et seq.

<sup>6</sup> Deoxyribonucleic acid, the substance responsible for the hereditary characteristics revealed by Watson and Crick in 1953.

<sup>7</sup> The three principal methods of production of genetically modified animals are microinjection of DNA in the pronucleus, the retroviral invection and the constitution in vitro of embryonic cells then injected into the host cells. In this regard, see R. Moufang, 'Patentability of Genetic Inventions in Animals' (1989) 20 *IIC – International Review of Industrial Property and Copyright Law* 823 et seq.

<sup>8</sup> That is living containers for the production of medicines.

In 2003, the mapping of the human genome was completed,<sup>9</sup> which promises significant opportunities for the medical field and for the protection of health.<sup>10</sup>

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<sup>9</sup> The human genome is constituted by the set of chromosomes contained in every cell, and contains the complete genetic heredity of a human organism, or, in other terms, the necessary genetic instructions for the development and management of every activity initiated by the organism. More correctly, the genome is the genetic material contained in a gamete, for which every somatic cell of a eukaryotic organism (typically diploid) such as humans, contain two complete genomes. Aploid organisms, like bacteria, have, instead, a single genome (usually a single circular DNA molecule). On this theme, see M. Ridley, *Genome*, New York: Harper Perennial, 2006; as well as the website of the National Human Genome Research Institute in the United States of America, accessed 12 December 2014 at <http://www.genome.gov>.

<sup>10</sup> The Human Genome Project was an international scientific research project, initiated in 1990 in 18 countries and coordinated by the United States of America, whose main objective was to determine the sequence of base pairs that make up DNA (in this regard, refer to Part II) and to identify and map all the genes of the human genome from the physical and functional point of view. The main objective of the Human Genome Project is to understand the function of genes belonging to the human race, but the project also studied various other non-human organisms. The genome of any individual (except that of monozygote twins and cloned organisms) is unique; thus, mapping the human genome means proceeding to the sequencing of the multiple variations of each gene. The first draft of the mapping of the genome was released in 2000, while the complete mapping was published in 2003 (except for some small residual intervals for which further research is being carried out, given that the methods of sequencing currently known do not allow their resolution). The researchers who carried out the basic sequencing were, on one hand, those of the Human Genome Project, with the conclusion of the sequencing being announced in June 2000 by the President of the United States Bill Clinton and the British Prime Minister Tony Blair; and on the other, those of a private company, Celera Genomics (founded and directed by the biologist Craig Venter), who announced the sequencing for the first time in April 2000. In February 2001 the results of both the studies were published, respectively in the magazines *Nature* and *Science*. The two sequences were not found to be significantly different from each other, and they were publicly available to the scientific community, meeting the demands made in this sense at an international level in the preceding months. What is more, following the sequencing of the nearly 3 billion base genes of the human genome is the discovery of single genes (which are held to be around 100,000 in all), or the parts of DNA responsible for the functioning of the human body, and if altered by illness (many of which, however, are monogenic, but are connected to a complex interaction between numerous genes and environmental factors). On this theme, besides what follows in Part II, see, among others: C. Kuppuswamy, *The International Legal Governance of the Human Genome*, London: Routledge,

With the advent of biotechnology, humanity is facing an extraordinary revolution, with profound implications for man and his relationship with other creatures.

Biotechnology, through its wide range of applications – relative, in particular to: (a) healthcare; (b) production and industrial processes; (c) the spheres of agriculture, breeding, veterinary and fish farming<sup>11</sup> – with the new awareness and opportunities which it provides, is having and will have an ever more significant impact on our way of life. Today, biotechnology seems able, for instance, to provide a solution for hunger in the world, to cure illnesses and improve the quality of life. Genetic and biological manipulation allows for diagnosis and gene therapy, as well as vaccines from plants and bio-medicines to create health treatments based on individual needs.<sup>12</sup>

In today's highly technological world, biotechnology is one of the most innovative and highly invested in industries for research, in the field of science. The main commercial applications of genetic engineering have been in the field of health care, agriculture and the environment. In the sector of health care, biotechnology has been used to produce medicines for the treatment of illnesses such as cystic fibrosis or various forms of cancer. With the help of biotechnology, diagnostic kits have also been produced. Currently, research is moving forward in regard to gene therapy,<sup>13</sup> which is aimed at correcting congenital pathologies. In agriculture, biotechnology uses recombinant DNA techniques in the process of

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2009, *passim*; N.S. Mosier and M.R. Ladisch, *Modern Biotechnology: Connecting Innovations in Microbiology and Biochemistry to Engineering Fundamentals*, New York: Wiley & Sons, 2009, p. 385 et seq.; F. Lenzerini, 'Biotechnology, Human Dignity and the Human Genome', in F. Francioni and T. Scovazzi (eds), *Biotechnology and International Law*, Oxford/Portland (USA), Hart Publishing, 2006, p. 285 et seq.

<sup>11</sup> For an extensive analysis on the subject, see European Commission Joint Research Centre – Institute for Prospective Technological Studies, 'Consequences, Opportunities and Challenges of Modern Biotechnology for Europe ('Bio4EU study')', 2007, accessed at: <http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=1470>.

<sup>12</sup> See B. Amani, *State Agency and the Patenting of Life in International Law*, Farnham (UK)/Burlington (USA): Ashgate Publishing, 2009, p. 20.

<sup>13</sup> Gene therapy consists in using nucleic acid as a therapeutic composition in medicine. The simplest method of use for gene therapy is to compensate for the abnormal expression of a gene. In this regard, see M.A. Croyle, 'Gene Therapy', in D.J.A. Crommelin, R.D. Sindelar and B. Meibohm (eds), *Pharmaceutical Biotechnology: Fundamentals and Applications*, New York: Informa Healthcare, 2007 (3rd edn.), p. 175 et seq.

raising animals or cultivating plants, to produce animals and plants with the required characteristics.<sup>14</sup> With regard to the environment, biotechnology has allowed for the production of transgenic microorganisms for the purpose of purifying the soil, water or air.

In order to protect the results of biotechnological research, legal regulations provide a system of protection based on the exclusive patent, which guarantees the inventor the right of exclusivity over the biotechnological finding.

In general, a biological patent is intended as that which is relative to an invention in the field of biology, the natural science regarding the study of life and living organisms. It may consist in a composition of matter, a method for obtaining or utilizing one or more of these, or a product which combines such elements. Contrarily, the hypothesis that a patent application may concern a naturally occurring biological substance in itself, regardless of whether it refers to a specific procedure or use associated with it, given that it has been sufficiently 'isolated' from its natural state, is one of the most controversial points of the debate on the subject.<sup>15</sup>

The genetic patent, according to the favored definition, is in reference to a specific and isolated genetic sequence, its chemical composition, the process used to obtain or use it, or a combination of these. Genetic patents fall under the broadest category of biological patents. What is more, the patentability of natural genetic sequences is not unanimous, and patents on genes have been allowed only in regard to isolated gene sequences with well-known purposes, and not for those naturally present in human beings or other living organisms.<sup>16</sup>

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<sup>14</sup> To date, examples of transgenic plants include tomatoes, potatoes, sugar beets and tobacco. In this regard and more generally on the theme of protection for plant varieties and so-called genetically modified organisms (GMO), see, among others, O. Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, Farnham (UK)/Burlington (USA): Ashgate Publishing, 2010 (Revised Edition), p. 155 et seq.; C. Brega, 'La tutela giuridica delle novità vegetali in Europa: dalle origini alla direttiva 98/44/CE sulla protezione giuridica delle invenzioni biotecnologiche', in G. Ghidini and G. Cavani (eds), *Brevetti e biotecnologie*, Rome: Luiss University Press, 2007, p. 155 et seq.

<sup>15</sup> On this point refer, extensively, to the following Parts.

<sup>16</sup> 'Federal Register – Utility Examination Guidelines – Comments and Responses', 5 January 2001; see also: Wikipedia.org, entries on *Biological patent* and *Gene patent*, respectively accessed 12 December 2014 at [http://en.wikipedia.org/wiki/Biological\\_patent](http://en.wikipedia.org/wiki/Biological_patent) and [http://en.wikipedia.org/wiki/Gene\\_patent](http://en.wikipedia.org/wiki/Gene_patent) (regarding the accuracy of the source, see J. Giles, 'Special Report: Internet Encyclopaedias Go Head to Head' (2005) 438 *Nature* 900 et seq.).

A human gene patent, finally, may be understood as that relative to a product or process which includes the single, specific human gene sequence. The sequence may be natural or synthetic, created in a laboratory through biotechnology (even if it is based on a natural human genetic sequence).<sup>17</sup>

In the United States of America, in 1980 the Supreme Court made a decisive contribution to the development of the biotechnology industry with its crucial decision in the case of *Diamond v. Chakrabarty*,<sup>18</sup> regarding the patentability of a microorganism not existing in nature and produced through genetic engineering. In particular, the Court ruled that 'anything under the sun made by man' is subject to patenting, identifying human intervention as a key element to distinguishing patentable inventions from non-patentable 'principles of nature and natural phenomena'.<sup>19</sup>

From the *Chakrabarty* ruling on, in the United States, and from the 1990s in Europe, thousands of patents related to inventions based on genetic material or information have been granted.<sup>20</sup> Some of these patents constitute important intellectual property assets for companies dedicated to the translation of biomedical research findings into diagnostic agents and life-saving therapies. They have played a key role in providing innovators with a sufficient period of exclusivity in order to recover the significant investments needed to develop and secure market interest for biotechnology products.<sup>21</sup>

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<sup>17</sup> On this and in general regarding the definition of a genetic patent, see the extensive considerations of C. M. Holman, 'Gene Patents Under Fire: Weighing the Costs and Benefits', in E. Arezzo and G. Ghidini (eds), *Biotechnology and Software Patent Law: A Comparative Review of New Developments*, Cheltenham, UK and Northampton, MA, USA: Edward Elgar, 2011, p. 260 et seq.; E. Arezzo and G. Ghidini, 'The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation' (2007) 76 *UMKC Law Review* 295 et seq., especially at 307 et seq.; see also, for a more limited definition: K. Jensen and F. Murray, 'Intellectual Property Landscape of the Human Genome' (2004) 310 *Science* 239 et seq.

<sup>18</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>19</sup> In this regard, refer to what shall be said extensively, in Part III.

<sup>20</sup> See C.A. Fowler, 'Ending Genetic Monopolies: How the TRIPs Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide' (2010) 25 *American University International Law Review* 1073 et seq.

<sup>21</sup> See J.H. Graham *et al.*, 'High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey' (2010) 24 *Berkeley Technology Law Journal* 1255 et seq.; C.M. Holman, 'Learning from Litigation: What Can Lawsuits Teach Us about the Role of Human Gene Patents in Research and Innovation?' (2009) 18 *Kansas Journal of Law and Public Policy*

Today, the companies focused on the development of personalized medicine and on pharmacogenomics<sup>22</sup> – technology which is widely held to be central to future pharmaceutical development and healthcare – hold genetic patents as essential to securing the revenues necessary to introduce these products to the market.

In 2001, the Patent and Trademark Office of the United States published formal Guidelines,<sup>23</sup> in which it illustrated its position on the basis of which inventions based on genes are patentable, given that there is sufficient human intervention to satisfy the ‘made by man’ standard dictated by the *Chakrabarty* decision.<sup>24</sup>

Outside the United States of America, there has been greater objection to the patentability of genetic material. In Europe this objection has caused some countries to exclude or limit the patentability of genes existing in nature. In 1998, in any case, following an arduous procedure, the European Union adopted a directive on biotechnology inventions,<sup>25</sup> through which Member states were asked to allow the patentability of genes. Some Member states, however, further limited the sphere or

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215 et seq.; K. Jensen and F. Murray, ‘Intellectual Property Landscape of the Human Genome’, cit., p. 239 et seq.

<sup>22</sup> Pharmacogenomics is the branch of biology which has developed from pharmacogenetics (regarding the study or clinical experimentation of genetic variations which result in different responses to medicines) and from the Human Genome Project, and can be defined as a science which is interested in the manner in which the knowledge of the human genome and its products (RNA and proteins) can be used in the discovery and development of new pharmaceuticals. This is based on the analysis of the entire genome of an individual in order to identify the genes that may be used as targets for new treatments, as well as individual genetic profiles from which the response to certain administered active ingredients may arise. See A. Squassina, M. Manchia, V.G. Manolopoulos, M. Artac, C. Lappa-Manakou, S. Karkabouna, K. Mitropoulos, M. Del Zompo and G.P. Patrinos, ‘Realities and expectations of pharmacogenomics and personalized medicine: impact of translating genetic knowledge into clinical practice’ (2010) 11 *Pharmacogenomics* 1149 et seq.; W. Kalow, U.A. Meyer and R.F. Tyndale (eds), *Pharmacogenomics*, New York: Taylor & Francis, 2005 (2nd edn).

<sup>23</sup> ‘Utility Examination Guidelines’, 66 *Fed. Reg.* 1092 (5 January 2001).

<sup>24</sup> In particular, the ‘Guidelines’ stated that the isolation of a DNA sequence existing in nature may lead to a product which is sufficiently different from the natural gene to render it patentable, citing a series of legal precedents which supported the patentability of biological molecules existing in nature, such as adrenaline (regarding the ‘Guidelines’ see, extensively, Part III).

<sup>25</sup> Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions.

applicability of these patents with respect to the American regulation. Nevertheless, all currently permit genetic patents.<sup>26</sup>

Despite these developments, patentability of genes remains a highly debated issue, even in the United States of America, and those opposed to it have been asking for some time that the possibility be brought to an end, or at least that the sphere of patents for innovations based on genetic sequences existing in nature be greatly limited.<sup>27</sup>

Biotechnology, further, also offers, besides the opportunities referred to above, new tools for information and operations regarding human life,<sup>28</sup> which raise fundamental questions regarding, on the one hand, the preclusive effects of genetic patents (in particular with regard to their impact on subsequent innovation and access to genetic diagnostic tests),<sup>29</sup> and on the other, the moral and bioethical profiles of the same.

Thus, despite the basic simplicity of the patent procedure, the complexity of today's technology, together with the pace at which it is evolving, leads to problems in patent law.

Further issues for inventors have arisen in regard to the development of patent legislation at the national and international levels. Today's inventor must face two problems that traditional mechanical inventors did not: the nature of the technology itself (which uses living material) and the deficiencies of international patent regulations.

The regulatory framework of the patent discipline has been conditioned, clearly, by the experience of man in forming and altering inanimate materials. Manufactured products were made from simple components. Patent protection was introduced in reference to the mechanical sector, concerning specific devices. Mechanical findings have certain basic characteristics, among which in particular is that of carrying

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<sup>26</sup> In this regard (referring for further details to Part IV), see *ex multis*: B.A. Brody, 'Intellectual Property and Biotechnology: The European Debate' (2007) 17 *Kennedy Institute of Ethics Journal* 69 et seq.

<sup>27</sup> For a systematic framework of the debate see C.M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, cit. in UKMC Law Review, 2007, accessed 5 January 2015 at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1090562](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1090562), p. 295 et seq.

<sup>28</sup> In this regard, see among others: Nuffield Council on Bioethics, 'Ethical Principles: Respect for Human Lives and the Human Body' (April 1995) *Human Tissue Ethical and Legal Issues* p. 39 et seq.

<sup>29</sup> On this point see, for instance: Department of Health & Human Services (USA) – Secretary's Advisory Committee on Genetics, Health, and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Test*', April 2010, accessed 12 December 2013 at [http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_patents\\_report\\_2010.pdf](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf).

out generally one function and of not reproducing itself in subsequent generations. Thus, it was reasonable that every technical application could be characterized by a simple list of structural characteristics, without the need to require the inventor to supply specific indications of its function or to foresee rules regarding subsequent generations. What is more, in the traditional model, the sequence of steps in order to arrive at the invention could be clearly defined.<sup>30</sup>

The policy underlying the patent system, as was first recognized within the U.S. Constitution<sup>31</sup> and therefore in models of the 1800s, was based essentially on a ‘quid pro quo’ mechanism: strong protection through an exclusive right granted for a limited time – aimed at supplying the inventor with financial incentive for research and development of the invention – in exchange for the public disclosure of information regarding the same.<sup>32</sup>

Biotechnology, which concerns living matter, poses significant challenges for patent law,<sup>33</sup> given that biotechnological inventions do not fall so neatly under the classical model, as do those of mechanics. On the other hand, the reasons at the foundation of patent protection, which in particular are the incentive to innovation and disclosure of information regarding inventions, according to the prevalent reconstruction are also deemed to be essential to the matter of biotechnological research – which

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<sup>30</sup> In this regard see, among others: G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, Cheltenham, UK and Northampton, MA, USA: Edward Elgar, 2010, p. 33 et seq.; S.A. Bent, R.L. Schwaab, D.G. Conlin and D. Jeffrey, *Intellectual Property Rights in Biotechnology Worldwide*, New York: Stockton Press, 1987, *passim*.

<sup>31</sup> On the basis of Article 1, Section 8(8), according to which: ‘The Congress shall have Power... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries’.

<sup>32</sup> In this regard, in addition to referring extensively below, as well as the Conclusions, see, *ex multis*, O. Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 41.

<sup>33</sup> For instance, according to some scholars, scientists and firms, the traditional assumption that the patent is granted as recognition for an invention appears to be reductive, due to the subtle line which exists between invention and discovery in the medical, pharmaceutical and agricultural fields. On this point see C.B. Onwuekwe, ‘Plant Genetic Resources and the Associated Traditional Knowledge: Does the Distinction between Higher and Lower Life Forms Matter?’, in J. Gibson (ed.), *Patenting Lives: Life Patents, Culture and Development*, Farnham (UK)/Burlington (USA): Ashgate Publishing, 2008, p. 139 et seq.

often requires significant investment and long time frames – justifying then the granting of patents in regard to their relative findings.<sup>34</sup>

Given that pre-existing legislation was not drafted with the particular characteristics of biotechnological inventions in mind, significant difficulties emerge in the application of patent law to such a constantly emerging and rapidly changing situation as that which is under discussion.<sup>35</sup> The conditions of novelty and originality are where much of the uncertainty lies with regard to the decision as to if and when biotechnological inventions are patentable. The condition of novelty requires that the invention not be available to others prior to the filing of the patent request. The issue is not if the subject of the request already exists, but if it is already known. The condition of originality requires, in addition, that the invention not be obvious to the average expert in the field.

There is a fundamental question that is posed regarding the patenting of biotechnological inventions concerning the interpretation of provisions of exclusion from patentability,<sup>36</sup> also in consideration of their close link with the moral/bioethical profiles<sup>37</sup> of biotechnology.

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<sup>34</sup> See Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 14. With regard to the debate on the theme, see below, as well as in the Conclusions.

<sup>35</sup> See, among others: B. Sherman, 'Patent Law in a Time of Change: Non-obviousness and Biotechnology' (1990) 10 *Oxford Journal of Legal Studies* 278 et seq.

<sup>36</sup> Provided by article 53 of the European Convention on Patents, in regard to which refer below, to the subsequent paragraphs.

<sup>37</sup> In general, morality can be defined as the system of rules, values and ideals considered universally valid and important as guidelines for action (F.W.A. Brom, J.M.G. Vorstenbosch and E. Schroten, 'Public Policy and Transgenic Animals: Case-by-case Assessment as a Moral Learning Process', in P. Wheale, R. von Schomberg and P. Glasner (eds), *The Social Management of Genetic Engineering*, Farnham (UK)/Burlington (USA), Ashgate Publishing, 1998, p. 249 et seq.; see as well: Wikipedia.org, entry *Morality*, accessed 12 December 2014 at <http://en.wikipedia.org/wiki/Morality>). As relevant as this concept is in this case, it is held to be, on the other hand, too broad; as such it is necessary to identify limits and declinations of the same as far as biotechnology is concerned. In this sphere, then, it is opportune to refer to the concept of bioethics, a discipline which deals with moral issues in connection with biological and medical research; in particular, it is defined as 'the systematic study of the moral dimensions – including moral vision, decisions, conduct and policies – of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting' (W.T. Reich (ed.), *Encyclopedia of Bioethics*, New York: MacMillan, 1995, 2nd edn, p. xxi). The coining of the term 'bioethics' is attributed to Fritz Jahr, who in 1927 spoke of 'imperative bioethics' in regard to

Though the science of biotechnology has been used for some time, in the United States of America and in Europe there is still confusion about the nature of the technology, its benefits and the limits which should be set in order to prevent related risks. In this regard, the most urgent and relevant issues of the debate concern the issues connected, in fact, to the risks that biotechnology poses, on the one hand, for the environment, and on the other, for human beings: the latter aspect, in light of the bioethical profiles it implies, constitutes the fundamental subject of analysis carried out hereinafter.

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man's exploitation of flora and fauna. Concerning the relation between bioethics and religion, almost all believers of any religious faith share the idea that that which surrounds us originates from an act of creation, that is divine intervention, supernaturally. This initial setting, as a consequence, leads to issues involving bioethics, which themselves have an effect on some of the most significant issues of human life (birth, sexuality, death). In traditionally Catholic countries, the role of Catholic bioethics is relevant. Official Catholic bioethics – contained in the documents of the Church Magisterium, in the works of authors found to be doctrinally in line with them and in the scientific community to which it refers – is founded on the principles of the sanctity and unavailability of life, holding that a human person is not the creator or owner of his own life. According to Catholic bioethics, each human has the right to life, from the moment of conception until his natural death. In favor of this argument, besides referring extensively to Part II, see *ex multis*, Wikipedia.org, entry *Bioethics*, accessed 12 December 2014 at <http://en.wikipedia.org/wiki/Bioethics>; B. Bryan, 'Biotechnology, Bioethics and Liberalism: Problematizing Risk, Consent and Law' (2003) 11 *Health Law Journal* 119 et seq.; Committee of Inquiry into Human Fertilisation and Embryology (coord. M. Warnock), *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, London: Her Majesty's Stationery Office, July 1984, accessed 12 December 2014 at [http://www.hfea.gov.uk/docs/Warnock\\_Report\\_of\\_the\\_Committee\\_of\\_Inquiry\\_into\\_Human\\_Fertilisation\\_and\\_Embryology\\_1984.pdf](http://www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into_Human_Fertilisation_and_Embryology_1984.pdf); H. Jonas, *The Imperative of Responsibility: In Search of Ethics for the Technological Age*, Chicago: University of Chicago Press, 1984 (Original edition: *Das Prinzip Verantwortung: Versuch einer Ethik für die technologische Zivilisation*, Frankfurt am Main: Insel-Verlag, 1979), *passim*; G. Fornero, *Bioetica cattolica e bioetica laica*, Milan: Mondadori, 2009 (2nd edn); Congregation for the Doctrine of the (Catholic) Faith, *Instruction Dignitas Personae on certain bioethical questions*, Vatican City, 8 September 2008, accessed 12 December 2014 at [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/rc\\_con\\_cfaith\\_doc\\_20081208\\_dignitas-personae\\_en.html](http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html); Catechism of the Catholic Church, 1997, accessed 12 December 2014 at [http://www.vatican.va/archive/eng0015/\\_index.htm](http://www.vatican.va/archive/eng0015/_index.htm).

## I.2 THE PATENT SYSTEM IN THE UNITED STATES OF AMERICA AND IN EUROPE

The biotechnology industry is currently fundamentally important both in the United States of America and in Europe, given that biotechnology is now essential for many economic sectors and produces considerable benefits for consumers.<sup>38</sup>

The patent system is the key link between science and technology, on the one hand, and law on the other.<sup>39</sup> In the past, the junction between these disciplines led to significant tension, emphasized by the fact that certain industrial sectors (for instance foods or pharmaceuticals) received more limited protection than others. This tension was sharpened when companies began to carry out cross-border activities and to request patents outside of their countries of origin.

While scientific and technical profiles remained the same throughout the world, in particular in the United States and in Europe, the differences between patent legislation led to a wide variety of rules on the requirements, procedures and context of the protection. In particular, the various national regulations were influenced by factors such as: (a) different reasons which justify patent protection;<sup>40</sup> (b) the concept of patent law as economic policy;<sup>41</sup> and (c) the relation between patent law and the legal system of the interested country as a whole.<sup>42</sup>

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<sup>38</sup> On this subject see, among others, G. Laurie, 'Biotechnology: Facing the Problems of Patent Law', in H.L. McQueen (ed.), *Innovation, Incentive and Reward*, Hume Papers on Public Policy vol. 5, Edinburgh: Edinburgh University Press, 1997, p. 46 et seq.

<sup>39</sup> See, in general, M. van Empel, *The Granting of European Patents, Introduction to the Convention on the Grant of European Patents, Munich, 5 October 1973*, Dordrecht (Netherlands)/Boston: Kluwer Academic Publishers Group, 1975.

<sup>40</sup> Traditionally there are four distinct theses: the thesis of 'natural right' or of 'intellectual property', that of 'compensation', that of 'incentive' and that of 'contract' or 'disclosure'. See O. Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 19. For a more wide framework of the various justifications underlying the patent system, see, among others, G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 33 et seq.

<sup>41</sup> Of the four theses above, today the dominant one would seem to be that which emphasizes the function of patents as tools of economic policy.

<sup>42</sup> The enforcement of patent rights falls under the context of national rules in civil procedure. Procedures connected to property law are also subject to administrative and legal control of their respective national authorities.

In general, as is known, a patent is an intellectual property right.<sup>43</sup> It is, essentially, a negative right given by the state, who grants the owner the right to exclude third parties from the use or exploitation of the invention without her/his consent.<sup>44</sup>

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<sup>43</sup> The fundamental discipline of intellectual property at an international level, as is well known, is provided in the 'Agreement on Trade Related Aspects of Intellectual Property Rights', signed in Marrakech on 15 April 1994, commonly known by the acronym TRIPS (accessed 12 December 2014 at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm)). The TRIPS Agreement is an international treaty promoted by the World Trade Organization, in order to establish a standard for the protection of intellectual property. The agreement was formalized by the WTO at the end of the meeting held in Marrakech in 1994, at the conclusion of the so-called Uruguay Round talks. The agreement establishes the requirements that adhering countries must respect for the protection of intellectual property, in the context of patents, copyright, trademarks, protected geographical indications, industrial design, etc. TRIPS also establishes guidelines for the application of the regulations on the matter of intellectual property, for appeals and conflict resolution procedures. On the basis of the agreement, protection and application of intellectual property laws should contribute to the progress of technological innovation and to easing the transfer and disclosure of technological knowledge, in order to reciprocally benefit manufacturers and users of the relative knowledge; pursuant to art. 7, in particular: 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. The TRIPS Agreement represents an attempt to close the gap and differences in the way in which intellectual property rights are protected at a global level, in order to regulate them in a context of common international regulation. To this end, it establishes a minimum level of protection that each country must guarantee with respect to the intellectual property rights of WTO members. On this theme, see, *ex multi*,: N. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, Alphen aan den Rijn (Netherlands): Kluwer Law International, 2010 (3rd edn); D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, London: Sweet and Maxwell, 2003 (2nd edn); D. Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement*, London: Routledge, 2002, *passim*.

<sup>44</sup> On economic profiles of the patent system, see in general, among others: V. Denicolò, 'Do Patents Over-compensate Innovators?' (2007) 22 *Economic Policy* 679 et seq.; S. Scotchmer, *Innovation and Incentives*, Cambridge (USA): MIT Press, 2004, *passim*; W.M. Landes and R.A. Posner, *The Economic Structure of Intellectual Property Law*, Cambridge (USA): Harvard University Press, 2003, p. 1 et seq.; V. Falce, *Profili pro-concorrenziali dell'istituto brevettuale*, Milan, Giuffrè, 2008 (also in regard to the philosophical foundation of the patent); D. Guellec and B. van Pottelsberghe de la Potterie, *The Economics of the*

The patent does not grant the property right of a specific tangible asset, which in the case of biotechnology would be for instance a specific sequence of DNA or protein.<sup>45</sup>

This confers a mere 'monopoly', more precisely a negative right of exclusion of third parties from the use of an invention relative to a product or process without the consent of the owner.

The patent exclusive, then, does not grant the owner the right to exploit the invention, but rather to prevent third parties from using the invention without her/his consent. The way in which this right is used, then, is usually entrusted to the control of the authority in charge of these matters.

The economic foundation of the patent system lies in the fact that it guarantees an incentive to innovation, representing a useful, at times indispensable, tool for the recovery of investments needed for the purposes of research and development of the invention.

In this sense, the main problematic issues within the patent system arise from the interests (seemingly conflicting) on the one hand of the innovators and/or investors, who want to recover their investments through protection obtained with the patent, and on the other of the other market operators (essentially competitors and consumers), who might be excessively damaged by the elimination of competition.<sup>46</sup>

Alongside such issues, but especially on the theme of biotechnological inventions of major significance, are the inherent profiles of risk of conflict between the granting of the exclusive and safeguarding the public interest, which may manifest in different hypotheses, from the

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*European Patent System*, Oxford: Oxford University Press, 2007; for an heterodox point of view, see also M. Boldrin and D.K. Levine, 'The Case Against Intellectual Property' (2002) 92 *American Economic Review* 209 et seq.

<sup>45</sup> On this theme, among others, see P. Grubb and P. Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, Oxford/New York: Oxford University Press, 2010 (5th edn), p. 3 et seq.; O. Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 2 et seq.; L. Bently and B. Sherman, *Intellectual Property Law*, Oxford/New York: Oxford University Press, 2009 (3rd edn), p. 335 et seq.; C.M. Holman, *Gene Patents Under Fire: Weighing the Costs and Benefits*, cit., p. 267 et seq.; D.R. Koepsell, *Who Owns You? The Corporate Gold-Rush to Patent Your Genes*, New York: Wiley-Blackwell, 2009; D. Magnus, A. Caplan and G. McGee (eds), *Who Owns Life?*, Amherst, NY: Prometheus Books, 2002.

<sup>46</sup> See S.J.R. Bostyn, 'A European Perspective on the Ideal Scope of Protection and the Disclosure Requirement for Biotechnological Inventions in a Harmonised Patent System; The Quest for the Holy Grail?' (2002) 5 *Journal of World Intellectual Property* 1013.

conflict with fundamental rights, public order or principles of morality, to the obstruction to access of findings by other researchers at the expense of the freedom of research and subsequent innovation, or of patients to the detriment of the right to health.<sup>47</sup>

Where it is recognized, patent protection guarantees a right of exclusivity in order to answer the question of 'property': if a company cannot recover the costs of the invention because the necessary information is available to anyone at no cost, the level of innovation is greatly reduced. In other words, the granting of the patent right is aimed at eliminating the problem of free riding.<sup>48</sup>

Patent protection leads to positive externalities, consisting in opportunities for third parties to use the information indicated in the patent; which may make inventors reluctant to provide this information, or lead to a reduction of investment in research and development. The positive effects of these externalities consist, instead, in the creation of opportunities for the original innovator, who can benefit from the new information developed by competitors, or, in the case of dependent inventions, to recover a part of her/his investment through revenues from patent licenses.<sup>49</sup>

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<sup>47</sup> In regard to these profiles refer extensively to the following Parts and the Conclusions.

<sup>48</sup> See K. Arrow, 'Economic Welfare and the Allocation of Resources for Invention', in R. Nelson (ed.), *Rate and Direction of Inventive Activity*, Princeton: Princeton University Press, 1962, p. 609 et seq. On the other hand, patent protection creates the so-called 'fishing problem': the possibility to obtain a patent (or the 'fish') pushes many individuals to invest their resources in order to obtain this result, but only one individual will succeed, while the investments of the others will be lost. Thus, the total social cost of the innovation is higher than that which is strictly necessary, giving rise to economic inefficiency. See S.M. Besen and L.J. Raskind, 'An Introduction to the Law and Economics of Intellectual Property' (1991) 5 *Journal of Economic Perspectives* 3 et seq.; F.M. Scherer and D. Ross, *Industrial Market Structure and Economic Performance*, Boston: Houghton Mifflin Company, 1990 (3rd edn), p. 624 et seq.; Y. Barzel, 'Optimal Timing of Innovations' (1968) 50 *Review of Economics and Statistics* 248 et seq.

<sup>49</sup> In this regard, among others, see S.J.R. Bostyn, *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation – Background study for the European Commission within the framework of the Expert Group on Biotechnological Inventions*, Brussels: European Commission, 2004 (accessed 12 December 2014 at [http://ec.europa.eu/internal\\_market/indprop/docs/invent/patentingdna\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/invent/patentingdna_en.pdf)); P.B. Joly, *Le rôle des externalités dans les systèmes d'innovation. Nouveaux regards sur le dilemme de la propriété intellectuelle* (1992) 43 *Revue économique* 785 et seq.

The objective of the patent system, both in the United States and in Europe, is to encourage innovation and the growth of new industries.<sup>50</sup> To these ends, the regulations grant the inventor rights over his invention in exchange for public 'disclosure' of the way it works. In this perspective, the interests of the inventor are balanced with those of the public. The patent system creates a monopoly in favour of private individuals, to whom appropriate limitations form a counterbalance. In the first place, a patent may be granted only for a finding that has the requirements of invention. What is more, the owner is granted exclusive rights regarding that specific invention. Finally, these exclusive rights, by their very nature, are temporary.

The patent right has a time limit, on the basis of the TRIPS<sup>51</sup> agreement (ratified by the United States and the European Union) and the European Patent Convention<sup>52</sup> of 20 years from the date of the application. The right is limited further by geographic terms, given that the patent is valid within the jurisdiction of the patent office from which it was issued.

In the United States, the Constitution provides the institution of a patent right granting Congress the power to promote progress of science and useful arts guaranteeing inventors, for a limited period of time, exclusive rights over their findings.<sup>53</sup> The provision simultaneously grants and limits power, in that Congress cannot ignore the grounds of the protection or override the limits imposed on it by constitutional dictates.<sup>54</sup>

In Europe, in order to guarantee states the possibility to compete at a global level, it was deemed necessary to grant the invention protection equivalent to that granted to other trading powers, such as, in particular,

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<sup>50</sup> In argument, see for all G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 33 et seq.; J.M. Aubrey, 'A Justification of the Patent System', in J. Phillips (ed.), *Patents in Perspective*, Oxford: ESC Publishing, 1985, p. 1 et seq.

<sup>51</sup> TRIPS Agreement, art. 33.

<sup>52</sup> 'Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973', signed in Munich on 5 October 1973, implemented on 7 October 1977, and modified several times, art. 63.

<sup>53</sup> United States Constitution, Article 1, Section 8(8). Concerning the U.S. regulations and connected problematic issues, see Part III.

<sup>54</sup> In this regard, see Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 41 et seq.

the United States.<sup>55</sup> Under this context, powerful and harmonized patent protection has been introduced.

To this end, the Convention of Strasburg of 1963<sup>56</sup> and the European Convention on Patents of 1973<sup>57</sup> were originally adopted. The former was aimed in general at the harmonization of the requirements for substantial patent rights, with optional exceptions connected to bioethics. The latter aimed at the construction of a patent system which could sustain the economic structure of the EEC (at the time), with obligatory exceptions with regard to bioethics. However, the question of whether the EPC weakens patent rights or not in the name of bioethical instances remains unanswered. Similarly, on this point, Directive 98/44/EC on biotechnological inventions is problematic regarding the same issue.<sup>58</sup>

Both in the United States and in Europe, as provided, in fact, by the TRIPS Agreement,<sup>59</sup> in order to be protected by an exclusive patent, an invention must respond to three fundamental requirements, which are:

<sup>55</sup> What is more, the issue is extremely controversial. In this sense, besides ethical profiles concerning this situation, appropriate remarks in the literature are relevant, which highlight how excessive patent monopolies may damage the free development of the competitive market. In argument, beyond what shall be said in the following Chapters, see among others, S. Anderman and A. Ezrachi (eds), *Intellectual Property and Competition Law – New Frontiers*, Oxford: Oxford University Press, 2011, p. 1 et seq.; G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 33 et seq. and 209 et seq.; J. Drexl (ed.), *Research Handbook on Intellectual Property and Competition Law*, Cheltenham, UK and Northampton, MA, USA, Edward Elgar, 2008, p. 1 et seq.; refer also to A. Stazi, *Intellectual Property Rights and Market Power in the European Union: The Fil Rouge of Consumer Welfare*, in *Comparazione e diritto civile*, June 2011 (accessed 12 December 2014 at [http://www.comparazione.diritto.civile.it/prova/files/stazi\\_intellectual.pdf](http://www.comparazione.diritto.civile.it/prova/files/stazi_intellectual.pdf)), p. 1 et seq.

<sup>56</sup> ‘Convention on the Unification of Certain Points of Substantive Law on Patents for Invention’, signed by the Member states of the European Council in Strasburg on 27 November 1963, and implemented on 1 August 1980.

<sup>57</sup> ‘European Patent Convention’ (EPC), cited. The States parties to the Convention are different from the EU states: Switzerland, Liechtenstein, Turkey, Monaco, Iceland, Norway, The Republic of Macedonia, San Marino, Albania and Serbia are part of the Convention but do not belong to the EU. The Convention established the European Patent Office (EPO).

<sup>58</sup> In reference to the regulations and related problematic profiles, see Part IV.

<sup>59</sup> Art. 27 of the TRIPS Agreement explicitly lists the criteria for patentability, mentioning novelty, originality and industriality, and refers indirectly to the selection criteria of the finding, stating that ‘patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial

- ‘novelty’;
- ‘originality’, or the inventive step (non-obviousness in the United States);
- ‘industriality’ (utility in the United States).

Further, the invention is required to provide ‘sufficient description’ (or disclosure) in the patent application.

One of the most significant questions asked at the base of patentability is the distinction between patentable inventions and non-patentable discoveries.

In the United States, the legislation does not give a clear definition of the concept of invention, nor does it make a distinction between an invention and a discovery.<sup>60</sup>

On the other hand, in case law a group of exceptions to patentability have been identified. In this sense, in the decision on the case *Diamond v. Diehr*<sup>61</sup> the Court

has undoubtedly recognized limits to section 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.<sup>62</sup> An idea of itself is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.

Further, in the ruling on the case *Gottschalk v. Benson*<sup>63</sup> it has been established that:

Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work. As we stated in *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130, ‘He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end’.

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application’; as far as concerns then the hypothesis of exclusion from patentability, see below the next paragraph.

<sup>60</sup> See 35 USC section 101.

<sup>61</sup> *Diamond v. Diehr*, 450 U.S. 175, 185 (U.S. Supreme Court 1981).

<sup>62</sup> See: *Parker v. Flook*, 437 U.S. 584 (U.S. Supreme Court 1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (U.S. Supreme Court 1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 U.S.P.Q. 280 (U.S. Supreme Court 1948).

<sup>63</sup> *Gottschalk v. Benson*, 409 US, at 67.

The decision in *Parker v. Flook*,<sup>64</sup> again, added that:

the rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect. The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious.

In the leading case *Diamond v. Chakrabarty*,<sup>65</sup> then, the Supreme Court has established the fundamental principle according to which 'everything under the sun made by man is patentable'. On the basis of U.S. case law, an invention is considered as such if it produces a useful, tangible and concrete result;<sup>66</sup> in other words, technical characteristics are not mentioned. This represents, without a doubt, a broad definition, but offers the advantage of clarity, and prevents the issues which arose in Europe in the attempt to determine the meaning of technical characteristics.<sup>67</sup>

The issue discussed up to this point is sometimes defined also as the 'product of nature doctrine'. On the basis of this doctrine, the products of nature as such are not patentable, while products derived from nature are. The principle has for some time been recognized in case law.<sup>68</sup> In the United States, for instance, in the ruling on the case of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the Supreme Court held that the composite or a composition of unknown materials simply discovered in nature is not patentable.<sup>69</sup> In the European Union, similarly, Directive

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<sup>64</sup> *Parker v. Flook*, 437 US, at 593.

<sup>65</sup> U.S. Supreme Court, *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 65 L. Ed. 2d 144, 100 S. Ct. 2204 (1980) (which cites S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)). Regarding the leading case, fundamental for the matter of biotechnology see Part III.

<sup>66</sup> See, for instance: *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1374-75, 47 U.S.P.Q.2D (BNA) 1596, 1602 (CAFC 1998), U.S. 142 L. Ed. 2d 704, 119 S. Ct. 851(1999).

<sup>67</sup> In regard to this point, see below.

<sup>68</sup> See S.J.R. Bostyn, *Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*, Eposcript Series, no. 4, Munich: EPO, 2001, p. 69 et seq.

<sup>69</sup> *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, cited. In particular, Judge Douglas explained, expressing the opinion of the majority of the Court, that 'patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are

98/44/EC on the protection of biotechnological inventions, in article 3(2), confirms the same concept, stating (positively) that: 'Biological matter that is isolated from its own natural environment or is produced through technical processes may be the subject of invention, even if it existed previously in its natural state'. In the same sense, the European Patent Office (EPO) 'Guidelines for Examination' clarify that:

If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an invention which may be patentable. ... To find a previously unrecognized substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable.<sup>70</sup>

In European law, the issue of the distinction between invention and discovery does not appear to be easily resolved, given that the legislation has yet to give a definition to each of the categories. This is not surprising, given that these concepts are subject to change. The EPO has traditionally held<sup>71</sup> that an invention must be technical in order to be considered patentable, regardless of the fact of whether or not it satisfies the requirements of patentability. The theme has long been considered hardly important, but with the developments in the field of biotechnology and software this position has become more and more problematic, especially considering that it is extremely difficult to define what

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manifestations of laws of nature, free to all men and reserved exclusively to none'. (333 U.S., 130).

<sup>70</sup> 'Guidelines for Examination in the European Patent Office', Munich, EPO, 2010 (accessed 12 December 2014 at <http://www.epo.org/law-practice/legal-texts/guidelines.html>), C IV.2.3.1, according to which, for instance, 'a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy'. See as well, on this theme, the 'Joint Statement' with which, already in 1988, the USPTO, the EPO and the Japanese patent office had stated that: 'Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds' (cited in: Nuffield Council on Bioethics, 'The ethics of patenting DNA: a discussion paper', July 2002, accessed 12 December 2014 at <http://www.nuffieldbioethics.org/patenting-dna>, p. 26, note 9).

<sup>71</sup> On the basis of art. 52 of the EPC.

'technical' means. The case law of the EPO, on this point, has stated that this concept is intended to be a finding that has technical characteristics, or provides a technical contribution.<sup>72</sup> This definition, however, appears essentially tautological and therefore irresolvable.<sup>73</sup>

In consideration of the uncertainty regarding the concept of invention in European law, emphasis has been put on the definition of discovery. It has been established that it consists in the discovery of something already existing in nature, but that has not already been discovered. The distinction from invention lies in the fact that in order to make a discovery the inventive act is not required. A discovery, in other words, is the mere knowledge relative to something existing in nature, while invention implies the ability of a human being to use this knowledge in a technical way, the so-called 'technical information'.<sup>74</sup>

Once the finding has been determined to be an invention in the aforementioned sense, in order to be patentable it should also satisfy the requirements of novelty, originality, utility and of sufficient description.

The requirement of novelty requires that the invention is, in fact, new. It must not already be available to others, in any form of public disclosure, publication or use before the date of filing of the patent application. The entirety of this previous knowledge is known as 'state of the art',<sup>75</sup> from which to be new an invention has to differ.<sup>76</sup>

The reasoning behind the requirement of novelty lies in the fact that that which is already known to the public is not new, and that which is already in the public domain cannot be the subject of a private monopoly.

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<sup>72</sup> See, for instance: Technical Board of Appeal, T 1173/97, *Computer program product/IBM*, 1 July 1998, EPO Official Journal, 1999, 609.

<sup>73</sup> See S.J.R. Bostyn, *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation – Background study for the European Commission within the framework of the Expert Group on Biotechnological Inventions*, cit., p. 12.

<sup>74</sup> See again, S.J.R. Bostyn, *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation – Background study for the European Commission within the framework of the Expert Group on Biotechnological Inventions*, cit., p. 14.

<sup>75</sup> Defined in the aforementioned 'Guidelines' of the EPO as 'everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application' (EPO Guidelines, C IV.6).

<sup>76</sup> See art. 54 EPC; 35 USC 102. Further, in practice the application of the principle is not always clear, given that it is not easy to have full knowledge of that which is the existing state of the art in the field.

A specific controversial issue on the subject of novelty is made with regard to chemical substances based on substances which exist in nature. A substance can be new if it is produced in a purer form than that which occurs naturally. On the other hand, this is not sufficient in and of itself: in order to integrate the requirement of novelty, it is necessary to provide proof of the fact that the modification of the parameters of the process produces different results.<sup>77</sup> Basically, novelty exists if the chemical substance in a purer form is also different in form or structure from that which exists in the state of the art. The same principle is applied, *mutatis mutandis*, for DNA. What is more, in case law it has been shown that a substance with an identical structure to that which occurs in nature may be considered new if that which already exists is not readily available to the public.<sup>78</sup>

For the requisite of originality or the inventive step, it is difficult to establish, but it is without a doubt connected to the issue of obviousness. The invention must not be obvious to the average expert in the field regarding that which is the state of the art.<sup>79</sup> In other words, the invention must not merely follow logically that which is already known to be the state of the art.<sup>80</sup>

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<sup>77</sup> See, for instance: T 0205/83, *Vinyl ester – crotonic acid copolymers/HOECHST*, EPO Official Journal, 1985, 363.

<sup>78</sup> See EPO, T 0206/83, *Pyridine herbicides/ICI*, EPO Official Journal, 1987, 5, which specifies that ‘a compound defined by its chemical structure can only be regarded as being disclosed in a particular document if it has been made available to the public in the sense of art. 54(2) EPC. ... The requirement is fulfilled if a reproducible method is described in the same document’. Similarly, in the United States, it has been determined that a previous reference excludes the novelty of an invention which is subsequently the subject of a patent application if the reference describes or discloses the same invention in a way that makes it public domain. In this sense, see for instance: *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *In re Brown*, 329 F.2d 1006, 1011 (CCPA 1964); *In re LeGrice*, 301 F.2d 929, 930 (CCPA 1962); in doctrine: S. Johnston, *Patent Protection for the Protein Products of Recombinant DNA* (1989) 4 *High Technology Law Journal* 257 et seq. In the sphere of DNA sequencing, the case law of the EPO determined that the mere fact that a sequence already existed in a library of DNA does not eliminate novelty, given that the sequence is not readily available to the public (See T 0301/87, *Alpha-interferons/BIOGEN*, EPO Official Journal, 1990, 335).

<sup>79</sup> Art. 56 EPC; 35 USC 103.

<sup>80</sup> According to the cited ‘Guidelines’ of the EPO: ‘The term “obvious” means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does

In the United States, the test to be carried out in order to analyze the inventive step or obviousness was indicated by the Supreme Court in the leading case *Graham v. John Deere Co.*, stating that ‘under section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or the non-obviousness of the subject matter is determined’.<sup>81</sup>

In Europe, the EPO uses the so-called ‘problem-and-solution approach’. At the basis of this approach, the nearest state of the art and the technical effect resulting from it is first examined. Then, the finding under discussion with its relative technical effect is identified. Finally, the objective technical problem to be resolved is defined, in order to pass from the nearest state of the art previous to the invention: if the solution of this technical problem is not obvious, the requirement of originality is deemed to be satisfied.<sup>82</sup>

The requirement of industriality, which up until a short time ago was not a particularly relevant theme in patent law, requires that the invention be subject to use in any industrial sector, including agriculture.<sup>83</sup>

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not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art’ (C IV-11.4).

<sup>81</sup> U.S. Supreme Court, *Graham v. John Deere Co. of Kansas City*, 148 USPQ 459, 467 (1966).

<sup>82</sup> See EPO ‘Guidelines’, CIV-11.5; Technical Board of Appeal, *Metal Refining/BASF*, 13 October 1982, EPO Official Journal, 1983, 13; T 0296/93, *Hepatitis B virus antigen production/BIOGEN*, 28 July 1994, EPO Official Journal, 1995, 627, where it is specified (7.4.4) that ‘the fact that other persons (or teams) were also working on the same project might suggest that it was “obvious to try” or that it was “an interesting area to explore”, but it does not necessarily imply that there was “a reasonable expectation of success”. “A reasonable expectation of success”, which should not be confused with the understandable “hope to succeed”, implies the ability of the skilled person to reasonably predict, on the basis of the existing knowledge before the starting of a research project, a successful conclusion to the said project within acceptable time limits. The more unexplored a technical field of research is, the more difficult is the making of predictions about its successful conclusion and, consequently, the lower the expectation of success’. In doctrine, see S.J.R. Bostyn, *Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*, cit., p. 74.

<sup>83</sup> Art. 57 EPC; 35 USC 101. On the basis of the EPO ‘Guidelines’: “Industry” should be understood in its broad sense as including any physical activity of “technical character” ... , i.e. an activity which belongs to the useful

The reasoning behind this requirement is that the invention which cannot be applied to industry does not provide benefits to society, and therefore is not worthy of patent protection. With the development of technological progress, the requirement of utility has taken on increased importance. In the field of biotechnology, the inventions concern DNA sequences without a known function. This has created doubt as to the interpretation of the utility requirement. The issue to resolve is whether, in order to satisfy this requirement, determining that the invention may potentially be used for specific purposes is sufficient or if the identification of at least one specific use is required.

In the United States, in 2001 the USPTO published a new version of the 'Utility Guidelines', according to which 'a claimed invention must have a specific and substantial utility. This requirement excludes "throw-away", "insubstantial", or "non-specific" utilities ...', specifying, in particular, that 'an invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (2) the utility is specific, substantial, and credible'.<sup>84</sup>

Similarly, in the recent case law of the EPO, a restrictive interpretation of utility has been provided.<sup>85</sup>

Such careful application of the requirement of utility, for instance, regarding the inventions concerning human stem cells, may hinder the granting of excessively broad patents, which block further technological developments, as well as the patentability in and of itself of fundamental research tools, supplying in this way an important 'filter' in order to

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or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article and could cover e.g. a process for dispersing fog or for converting energy from one form to another' (IV 5.1). It is, in particular, specified that: 'Methods of testing generally should be regarded as inventions susceptible of industrial application and therefore patentable if the test is applicable to the improvement or control of a product, apparatus or process which is itself susceptible of industrial application. In particular, the utilization of test animals for test purposes in industry, e.g. for testing industrial products (for instance for ascertaining the absence of pyrogenetic or allergic effects) or phenomena (for instance for determining water or air pollution) would be patentable' (IV 5.2).

<sup>84</sup> 'USPTO Guidelines for Examination of Applications for Compliance with the Utility Requirement' (2001) 66 Federal Register, 5 January, § 1092 et seq.

<sup>85</sup> EPO Opposition Division, *ICOS/SmithKline Beecham and Duphar International Research*, 20 June 2001, EPO Official Journal, 2002, 293.

prevent monopolization of entire fields of research through excessively broad and unspecific patents.<sup>86</sup>

The application of requirements for patentability may indirectly influence the sphere of patent extension. This must be broad enough in order to compensate for the costs of the invention. If the field of the invention is not broad enough, minor improvements may be made by third parties without violating the patent, at the expense of the possibility to recover investments made for the achievement of the invention itself. If the field is too limited, the exclusive right may have a preclusive effect on technological development.

A limited field has, from an economic point of view, the advantage of leaving more room for subsequent innovation and competition, after the original innovation. On the other hand, increased competition may also lead to higher social costs, in the sense that it may lead, for instance, to the duplication of entry costs, inefficient production, etc.<sup>87</sup>

A broad field has the advantage of supplying better protection to the original creator with regard to minor improvements and from *tout court* second generation creators. This leads the original creator to disclose the invention, with the related positive effects in terms of the reduction of social costs of innovation. On the other hand, a broad field inhibits new entries and subsequent creators, reducing competition. When the field of exclusive patents is broad, there may be a tendency to disinvest, given

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<sup>86</sup> On this point, see P.L.C. Torremans, 'Patentability of Human Stem Cell or Synthetic Biology Based Inventions', in E. Arezzo and G. Ghidini, *Biotechnology and Software Patent Law: A Comparative Review of New Developments*, cit., p. 288 et seq.; R.J. Aerts, 'Biotechnological Patents in Europe – Functions of Recombinant DNA and Expressed Protein and Satisfaction of the Industrial Applicability Requirement' (2008) 39 *IIC* 283 et seq.; K. Bergman, G. Graff, 'The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development' (2007) 25 *Nature Biotechnology* 419 et seq. In this regard, clearly, besides economic situations which pose fundamental ethical questions, regarding which one may refer below to the subsequent paragraphs.

<sup>87</sup> In virtue of the fact that the field is limited, and that more operators are attracted to entry to the market with competitive products, there is less profit for the original creator. This may lead to a reduction in the incentive to innovation, or to a tendency to keep it secret; this secret may lead to duplication of investment in research and development, given that more people will be occupied in 'reinventing the wheel', in the absence of knowledge available to the public. On this theme, see V. Denicolò, 'Patent Races and Optimal Patent Breadth and Length' (1996) XLIV *The Journal of Industrial Economics* 249 et seq.; H.F. Chang, 'Patent Scope, Antitrust Policy, and Cumulative Innovation' (1995) 26 *Rand Journal of Economics* 34 et seq.

that the broadness of the field makes it less interesting for potential competitors to enter the market or invest in improvements or in other innovations based on the original invention. The consequence of this may be a preclusion of technological development.<sup>88</sup>

Thus, according to the preferable reconstruction, it is better for the system to be more open, though it may create the inefficiencies referenced above, given that such a system may allow for the preservation of the opportunity for technological progress.<sup>89</sup>

In addition to the requirements of novelty, originality and utility, both in the United States and in Europe, there are further limits to patentability, among which that concerning the 'sufficient description' of the invention in the patent application is particularly relevant. Based on this principle, the invention must be described in a sufficiently clear manner to allow the average expert in the field to put it into practice.<sup>90</sup>

The reasoning is that the owner of the patent obtains a temporary monopoly on the invention in exchange for the fact of making the way in which it functions known, which is called disclosure.<sup>91</sup>

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<sup>88</sup> See, among others, H.F. Chang, 'Patent Scope, Antitrust Policy, and Cumulative Innovation', cit., p. 52; S. Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' (1991) 5 *Journal of Economic Perspectives* 29 et seq.

<sup>89</sup> See S.J.R. Bostyn, *A European Perspective on the Ideal Scope of Protection and the Disclosure Requirement for Biotechnological Inventions in a Harmonised Patent System; The Quest for the Holy Grail?*, cit., p. 1016.

<sup>90</sup> Art. 83 EPC; 35 USC 112.

<sup>91</sup> See EPO Technical Board of Appeal, T 0169/83, *Wallelement/ Vereinigte Metallwerke*, decision 3.2.1 of 25 March 1985, EPO Official Journal, 1985, 193; U.S. Supreme Court, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 109 S.Ct. 971, 9 USPQ2d 1847 (1989), which reveals, in particular, how: 'From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy. ... The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and not obvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. [The inventor] may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but upon expiration of that period, the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and profit by its use'. See also U.S. Supreme Court, *Grant v. Raymond*, 31 U.S. (6 Pet.) 218 (1832).

The sufficient description of the claims contained within the patent application is significant to the definition of the field of patent monopoly.<sup>92</sup> The patent may be granted only if and in as much as the description indicates the method for reproducing that which the inventor claims.<sup>93</sup> Adequate disclosure of the invention, then, is the quid pro quo of the granting of a patent to the owner for temporary monopoly over his invention.

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<sup>92</sup> What is more, from the systematic point of view it is useful to distinguish the context of the invention from the context of protection, given that the latter concept is used in relation to the phase following the granting of the patent, in particular in the context of a request for violation of the patent and any application of the equivalency doctrine. See also, for reference to European and United States case law on the subject, S.J.R. Bostyn, *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation – Background study for the European Commission within the framework of the Expert Group on Biotechnological Inventions*, cit., p. 28 ss., and S.J.R. Bostyn, *Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*, cit., p. 145 et seq.; C.M. Holman, *Gene Patents Under Fire: Weighing the Costs and Benefits*, cit., p. 268; J.M. Mueller, *Patent Law*, New York: Aspen Publishers, 2009 (3rd edn), p. 332 (which, citing Judge S. Rich, recalls that ‘the name of the game is the claim’); M.J. Adelman, R.R. Rader, J.R. Thomas, H.C. Wegner, *Cases and Materials on Patent Law*, St. Paul, Minnesota: West Group, 1998, p. 567 et seq. (where it is specified that: ‘The enablement requirement serves to delimit the boundaries of patent protection by ensuring that the scope of a patent claim accords with the extent of the inventor’s technical contribution’); D.S. Chisum, C.A. Nard, H.F. Schwartz, P. Newman, F.S. Kieff, *Principles of Patent Law*, New York: Foundation Press, 1998, p. 163 et seq.; J.H. Barton, ‘Patent Scope in Biotechnology’ (1995) 26 *IIC* 605 et seq.

<sup>93</sup> In reference to the sphere of extension of patent exclusivity, in the ruling of the House of Lords regarding the *Biogen* case Lord Hoffmann stated that ‘if the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. ... On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them. Thus if the patentee has hit upon a new product which has a beneficial effect but cannot demonstrate that there is a common principle by which that effect will be shared by other products of the same class, he will be entitled to a patent for that product but not for that class, even though some may subsequently turn out to have the same beneficial effect. ... On the other hand, if he has disclosed a beneficial property which is common for the class, he will be entitled to a patent for all products of that class even though he has not himself made more than one or two of them’ (*Biogen Inc. v. Medeva plc*, decision of 31 October 1996, [1997] *RPC* 1, 48-49). In the same sense, it seems to move in the same direction of the EPO case law; see for instance: Technical Board of Appeal, T 0694/92, *Modifying plant cells/*

In this regard, as far as, in particular, the issue of accessibility to the public of biological material is concerned, the tool which prevails in international practice consists in the depositing of samples of the specific organism claimed in the patent application with the designated authorities delegated for this purpose, based on the Treaty of Budapest of 1977.<sup>94</sup>

### I.3 UNPATENTABLE INNOVATIONS: THE PROVISIONS OF THE TRIPS AGREEMENT AND DIFFERENCES BETWEEN PATENT MODELS

The TRIPS Agreement, in article 8, para. 1, considers<sup>95</sup> the possibility that the States parties to it, when forming or modifying their legislative or regulatory provisions, may adopt the measures necessary to ensure the protection of public health and nutrition, and to promote the public interest in spheres which are fundamentally important for their social-economic and technological development, as long as those measures are compatible with the provisions of the Agreement.

On the basis of article 27, para. 1, of the same Agreement, the attainment of patents and enjoyment of relative rights are not subject to discriminations on the basis of the place of invention, the technological sector or whether products are imported or of local production.

The provisions regarding non-discrimination among the various fields of technology subject to patent protection have particularly relevant effects for the development of biotechnology. As a consequence, on one hand, the use of biological materials of plant, animal or human origin in and of itself does not exclude patentability of the finding (where they satisfy the conditions laid down in that Article); on the other, ethical or environmental limits to patentability of biotechnology, though legitimized

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*MYCOGEN*, ruling 3.3.4, 8 May 1996, EPO Official Journal, 1997, 408. In doctrine, see Bostyn, *Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*, cit., p. 190 et seq.; R.P. Merges, *Patent Law and Policy*, Virginia: The Michie Company, 1992, p. 515 et seq.

<sup>94</sup> 'Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure', Budapest, 28 April 1977. The term 'microorganisms', which the Treaty provides no definition for, has been in practice interpreted in an extensive sense, including not only bacteria, fungi, algae and yeasts, but also plant, animal and human cells, seeds, DNA or RNA samples and oncogens.

<sup>95</sup> In the first part relative to general provisions and fundamental principles.

by the Agreement itself,<sup>96</sup> may be introduced into national regulations and applicative practices only as exceptions which are defined and limited by a general rule, with the result that they must be interpreted in a restrictive sense.<sup>97</sup>

Article 27, para. 2, provides that the States parties to the Agreement may exclude patentability for inventions whose commercial use in their territory must be inhibited for reasons of public order or morality, as well as to protect human, animal or plant life or health or to prevent serious environmental damage, as long as the exclusion is not dictated solely by the fact that its use is prohibited by their legislation. It is advisable, therefore, that the States reconsider their pre-existing legislation, should it be in conflict with this provision.<sup>98</sup>

In the context of regulations on intellectual property, the clauses which safeguard public order<sup>99</sup> and morality<sup>100</sup> are traditionally considered a sort of formula of style destined to remain mostly unimplemented. These profiles fall under the competence of national political authorities (and not technical offices such as that of patents), which may intervene through implementation or marketing prohibitions regarding the inventions in question. The argument is based on the rules, including those of the TRIPS Agreement,<sup>101</sup> which confer rights to owners of exclusive

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<sup>96</sup> Pursuant to the provisions referenced in this paragraph.

<sup>97</sup> See, for a broad analysis of the classification of the principle of non-discrimination in the sphere of the TRIPS Agreement, T. Sommer, 'The Scope of Gene Patent Protection and the TRIPS Agreement – An Exclusively Nondiscriminatory Approach?', (2007) 38 *IIC* 30 et seq.

<sup>98</sup> In this way, a system of decentralized and distributed policy is put in place, which has been defined in doctrine as 'neo-federalist', with a broad sphere of discretion left to the States parties to the Agreement. See, among others, G.B. Dinwoodie and R.C. Dreyfuss, 'International Intellectual Property Law and the Public Domain of Science' (2004) 7 *Journal of International Economic Law* 435 et seq.

<sup>99</sup> The concept of public order is understood as the totality of fundamental regulations regarding ethical and political principles at the base of a specific legal system, with respect to which it is not possible to vary without putting its very existence in jeopardy. See C. Kuppaswamy, *The International Legal Governance of the Human Genome*, cit., p. 137; Gervais, *The TRIPs Agreement: Drafting History and Analysis*, cit., p. 222.

<sup>100</sup> Or rather, the totality of conventions and ethical values constituting the morals of a social group of a specific time and place. With regard to the concepts of morals and morality, besides referring to what has been said above, please see Wikipedia.org, entry *Morality*, cit.

<sup>101</sup> TRIPS Agreement, art. 28, on the basis of which: '(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's

patents, related only to the exclusion of use of the protected invention by anyone, and not to the creation and commercial use of the invention itself. According to this perspective, the patent must be considered a neutral tool with regard to the discipline based on principles connected to fundamental rights, morals, public order, environmental protection, and so on, derived from the distribution of the products or patent processes. Such a discipline may take precedence over the granting of a patent and, vice versa, nothing prevents, even where it is not granted, products and processes based on controversial technology from being put into circulation.<sup>102</sup>

In any case, the development of biotechnology has led to a broad debate on the conformity of biotechnological inventions to public order and morality, forcing different patent offices to respond to the legality of the patenting of such inventions. In particular, the EPO, starting with the *Harvard Onco-Mouse* decision,<sup>103</sup> considered the concept of public order in a broad sense, as the totality of principles which in a specific legal system has the purpose of protecting basic values of the collective. This approach of the EPO, then, appears to be in contrast with the theory of irrelevance of the aforementioned fundamental principles on the matter of patentability of biotechnological inventions.

Once again, in article 27, para. 3, the States parties to the Agreement are allowed (but not required) to exclude from patentability: (a) diagnostic, treatment and surgical methods for the treatment of man or animals; (b) plants and animals, except for microorganisms, and essentially biological processes for the production of plants or animals, except for processes which are not biological or microbiological. However, the

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consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process'.

<sup>102</sup> In this regard, among others, see G. Van Overwalle, 'Biotechnology and patents: global standards, European approaches and national accents', in D. Wüger and T. Cottier (eds), *Genetic Engineering and the World Trade System*, Cambridge: Cambridge University Press, 2008, p. 77 et seq.

<sup>103</sup> A genetically modified mouse from the University of Harvard modified in order to make it predisposed to contracting cancer, and in this way to serve as a test subject for the study of the illness. See Examining Division, *Onco-Mouse/HARVARD*, 14 July 1989, EPO Official Journal, 1989, 451.

States are required to provide protection for plant varieties either through patents or an effective *sui generis* system or some combination of the two.

In regard to this provision, with specific reference to (b), it has been shown that the situation does not refer specifically to biotechnology, but rather is more broadly applicable to all research and/or industrial activities which involve the use of plants and animals. In particular, regarding the patenting of products the regulation allows for prohibitions regarding plants and animals considered as a whole, with the exception of microorganisms, while the processes not subject to protection are those which are essentially biological for the production of plants or animals, except also those which are microbiological and non-biological processes. Such broad power is still limited in part by the regulation which provides the obligation of States to introduce a tool for protection of the so-called plant varieties.<sup>104</sup>

What is more, the prevalent interpretation of article 27, para. 3(b), implies that a large number of biotechnological inventions related to the animal and plant world result in patentable effects.

Concerning process patents, the prohibition of exclusion from patentability of microbiological processes, contrary to that which is provided for those which are essentially biological, act in order that techniques of genetic engineering are almost all patentable, given that they use and create microbiological material. The context of patentability of genetic engineering is broadened, on the one hand, from the extensive definition of the material concept of microbiological material, also for the difficulty at a scientific level of a clear distinction between microbiology and biology; on the other, the practice of patent offices to deem that the existence of human intervention for the development and completion of processes of genetic engineering does not permit them to be held as essentially biological.

With regard to product patents, the same considerations in substance are valid. In particular, there is a clear consensus that DNA, beyond the fact that it is living matter responsible for the transmission of hereditary characteristics, is in any case a chemical substance, or a particular microbiological material, and therefore patentable. Animal or plant genes, in turn, may be patentable in that they are fragments of a chemical substance. This position finds support in practice, both in the decisions of

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<sup>104</sup> The reason for the provision of obligation of protection for specific taxonomic classifications of plants is traceable back to the 'International Convention for the Protection of New Varieties of Plants', so-called UPOV Convention, adopted in Paris on 2 December 1961 and last modified in 1991.

patent offices and as far as the filing of microorganisms on the basis of the Treaty of Budapest are concerned.

The TRIPS Agreement, therefore, does not provide a unified standard which outlines the limits of the concept of invention: this has led various States parties to the Agreement to adopt their own specific definitions (except with respect to the requirements of patentability cited from article 27, para. 1).<sup>105</sup>

In particular, the Agreement does not take material existing in nature into consideration, and it does not include genetic material among the exceptions of patentability.<sup>106</sup> Thus, single States parties to the Agreement, characterized by different levels of social and economic development, must face complex issues of patentability on a case-by-case basis.<sup>107</sup>

The generic terminology used by the TRIPS Agreement – which does not specifically mention biotechnology in any provision<sup>108</sup> – has led to

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<sup>105</sup> See C.A. Fowler, 'Ending Genetic Monopolies: How the TRIPs Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide', cit., p. 1073 et seq.; D. Matthews, 'Globalising intellectual property rights: the TRIPs Agreement', cit., p. 46 et seq.

<sup>106</sup> See, among others: G. Dinwoodie and R. Dreyfuss, 'International Intellectual Property Law and the Public Domain of Science', cit., p. 435 et seq.; M. Khor, *Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues*, London/New York: Zed Books; Penang, Malaysia: Third World Network, 2002, p. 70 et seq.

<sup>107</sup> In this regard, see World Health Organization, 'Genetics, Genomics and the Patenting of Dna: Review of Potential Implications for Health in Developing Countries', 2005, accessed 12 December 2014 at <http://www.who.int/genomics/FullReport.pdf>, p. 21 et seq.

<sup>108</sup> Vice versa, the agreement projects preceding the so-called 'Dunkel Draft' ('Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations', doc. MTN.TNC/W/FA of 20 December 1991, or the 'Dunkel Draft,' from the name of the CEO of GATT at that time, a document which the definitive text of the TRIPS Agreement has remained almost entirely unchanged), considered an option, introduced upon the request of developing countries, according to which, on the subject of biotechnological inventions, the limits of patentability established at a national level and beyond would have been admissible with respect to those provided by the Agreement for the generality of inventions. The failure to include this clause in the final text is due to the opposition of industrialized countries, which held that it might hinder the development of the emerging biotechnology sector. On the other hand, it has been highlighted how the fact that during negotiations biotechnological patents were considered by developing countries as phenomena to be avoided or in any case limited, or rather in terms of exemptions and exceptions to the forms of protection guaranteed by the Agreement, has impeded a specific reflection on the

many differences in national patent legislation regarding biotechnology and genetic material.<sup>109</sup> The States parties to the Agreement have adopted a variety of approaches in the interpretation and implementation of their respective patent laws on the matter, in an attempt to conform to international law while maintaining specific national disciplines.<sup>110</sup>

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issues connected to the theme of patentability of biotechnological inventions, which would have in theory been able to lead to solutions which took into consideration their particularity, for instance through a provision of further requirements for granting patents in this field, or the promotion of a sort of specific collateral agreement, etc. (for a detailed diachronic reconstruction of the approval process and of the inspired reasoning behind the TRIPS Agreement and in particular the provisions referenced, see among others: N. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, cit., especially p. 245 et seq.).

<sup>109</sup> Regardless, it is clear that the TRIPs Agreement holds significant importance for the discipline of biotechnology. The objectives that it indicates as fundamental for the protection of intellectual property, in fact, consists essentially in the promotion of technological innovation and in the transfer and distribution of technology (see art. 7, cit.). The Agreement is based on the assumption that only adequate and effective protection of intellectual property can lead to technological transfer in favour of less advanced countries. In the sphere of biotechnology, for instance, this means the actual recognition and respect of countries for a patent regarding recombinant DNA techniques, which make agricultural plants resistant to drought, representing the conditions necessary to make this technology available to the country itself. The perspective adopted in the Agreement, therefore, is fundamental, and significant resistance from some countries arises – in particular from those which are less developed – with regard to the implementation in their legal systems of regulations which are completely compliant with the Agreement. Such a perspective, in fact, implies that (at least in this moment in history) the protection of intellectual property in less advanced countries works almost completely in favour of companies of industrialized countries, given that the former do not have the adequate local industry to benefit from it. On this theme, see, among others, G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 247 et seq.; C.M. Correa, *Intellectual Property and Competition Law – Exploring Some Issues of Relevance to Developing Countries*, ICTSD, Issue Paper No. 21, 2007, accessed at [http://ictsd.net/downloads/2008/06/corea\\_oct07.pdf](http://ictsd.net/downloads/2008/06/corea_oct07.pdf).

<sup>110</sup> In this sense, the main issue both in the United States and in Europe regarding inventions based on genetic material is in relation to the doubt that only relative processes are patentable or also the genes themselves. In this regard, besides that which will be said hereafter, see S. Soini *et al.*, ‘Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues’ (2008) 16 *European Journal of Human Genetics* S10 et seq.; World Health Organization, ‘Genetics, Genomics and the Patenting of Dna: Review of Potential Implications for Health in Developing Countries’, cit., p. 26 et seq.

In general, unlike the United States of America, many European States provide a list of material which is not considered to be subject to patent protection. Though certain materials may constitute the substrata for an invention, they are in any case considered unpatentable inventions pursuant to patent legislation.

As far as patent requirements are concerned, both in the United States and European models, as previously mentioned, the reasoning for the exclusion lies overall in the fact that, as they are not inventions which are applicable at an industrial level, they would not produce benefits for society, and therefore it is not worthwhile to grant the applicant the status of monopoly for its use.

With specific reference to patentable material, then, in Europe, inventions which are essentially biological and those contrary to public order or morality are also excluded from patent protection. In any case, it should be noted that the single European states differ in their approach to patentable subject matter and application of the relevant discipline.

Given that the U.S. and European patent systems have basically the same objectives, one could argue that they operate in substantially the same way. In reality, there are significant differences between the two systems.

The first fundamental difference lies in the fact that in the United States the origin of intellectual property is in the Constitution, in that the Constitution grants Congress the power to adopt regulations relative to patents.<sup>111</sup> On the contrary, in European countries the origin of intellectual property is national and – except for the principle of intellectual property protection introduced at article 17, para. 2 of the ‘Charter of Fundamental Rights of the European Union’<sup>112</sup> – there is not a directly binding legislation or centralized mechanism of enforcement.<sup>113</sup>

In the United States, patents are granted by the federal government, through the United States Patent Office, a centralized institution. In the

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<sup>111</sup> United States Constitution, Article I, Section 8, Clause 8, so called ‘Copyright Clause’, grants Congress the power: ‘To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries’.

<sup>112</sup> Charter of Fundamental Rights of the European Union, proclaimed on 7 December 2000 in Nice, and afterwards, in an adapted version, on 12 December 2007 in Strasbourg; The Charter actually, given the Treaty of Lisbon, has the same legal value as the Treaties (see below, especially in Parts III and V).

<sup>113</sup> At least until the entry into force of the ‘European Union patent’, approved by the European Parliament on 11 December 2012, which would constitute a single patent right valid for the entire territory of the EU (see in Part IV).

European Union, patents are granted by the European Patent Office, which is not an EU institution, but rather functions on the basis of the European Patent Convention.

United States public policy basically considers patents a tool for the creation of new industries. Besides this, the European legal system regulates them, both by promoting and limiting them, for the adequate development of the internal market.<sup>114</sup>

In the United States, requirements for patentability and identification of patentable material are derived overall from the work of the case law. In Europe, they are provided at a regulatory level within the European Patent Convention, as well as, of significance here, in Directive 98/44/EC.

In general, in the United States, the limits of patentable material appear to be well defined,<sup>115</sup> given the legislation drafted in positive terms and the 'activism' of case law in its interpretation.

In Europe, both in the European Patent Convention and Directive 98/44/EC, the provisions relative to unpatentable materials are drafted in negative and complex terms, with the relative legal uncertainty for aspiring patent owners.

In the United States, there is a clear distinction between the granting of the patent and use of the invention. On the contrary, in Europe it is held that where use is contrary to public order or morality the patent may not be granted.

The origin of the policy and the history of patent regulation in the United States indicate how in that system there is not a patent regime based on morality. Though the courts may have sometimes denied patents for inventions which were considered immoral, in fact these cases fall under two possible hypotheses: inventions used to defraud buyers and machines used for gambling. As far as the Patent Office is concerned, the only case relevant to a denied patent on the basis of moral considerations

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<sup>114</sup> In this regard, see *ex multis*: S.W. Halpern, C.A. Nard and K.L. Port, *Fundamentals of US Intellectual Property Law. Copyright, Patent, Trademark*, Alphen aan den Rijn (Netherlands): Kluwer Law International, 2010 (3rd edn), p. 1 et seq.; T. Cook, *EU Intellectual Property Law*, Oxford/New York: Oxford University Press, 2010, p. 1 et seq.; C. Seville, *EU Intellectual Property Law and Policy*, Cheltenham, UK and Northampton, MA, USA, 2009, p. 1 et seq.; H.C. Hansen, *US Intellectual Property Law and Policy*, Cheltenham, UK and Northampton, MA, USA, 2006, p. 1 et seq.

<sup>115</sup> Even with the lack of which will be spoken of hereafter.

is that which was requested in 1997 by Stuart Newman and Jeremy Rifkin for the creation of a human-animal chimera.<sup>116</sup>

On the other hand, in Europe the history of patent legislation indicates that morality plays a broader role, even with all the issues it presents (concepts, limitations, time frame, etc.).<sup>117</sup> Both the European Patent Convention and Directive 98/44/EC provide exclusion from patentability for reasons of public order or morality.<sup>118</sup>

With reference to the matter of biotechnology, United States case law has interpreted the criteria of general patent legislation as suitable to allow for protection of biotechnological inventions, regulating patentability of the forms of life according to the general protection regime.

On the contrary, the European Patent Convention, as the Strasbourg Convention, prohibited the patenting of plant<sup>119</sup> or animal varieties, a tendency continued in Directive 98/44/EC, which, further, provided broad exclusions, specifying the requirements of patentability for biotechnological inventions, with the result of a dual framework of patent protection (general and biotechnological).<sup>120</sup>

#### I.4 THE ISSUE OF THE ROLE OF MORAL EVALUATION IN PATENT RIGHTS

The debate on legal, social and moral issues connected with today's biotechnology gives rise to very different points of view – and underlying interests – not only between individuals within the patent system, in particular scientists, lawyers and economists, but also in the general collective, who ask who determines the methods of use of technology and who will reap the benefits.

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<sup>116</sup> In this regard, refer to Part III.

<sup>117</sup> See R.P. Merges, 'Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies' (1988) 47 *Maryland Law Review* 1051 et seq.

<sup>118</sup> See A. R. Chapman, 'The Ethics of Patenting Human Embryonic Stem Cells' (2009) 19 *Kennedy Institute of Ethics Journal* 261 et seq.; R.K. Seide and C. Stephens, 'Ethical Issues and Application of Patent Laws in Biotechnology', in D. Magnus, A.L. Caplan and G. McGee (eds), *Who Owns Life?*, cit., p. 59 et seq.

<sup>119</sup> Previously protected by the UPOV Convention and today on the basis of EC Regulation no. 2100/94.

<sup>120</sup> On these aspects, besides referring below, see O. Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 2 et seq. and 155 et seq.

The fundamental question, in this regard, is if public control over these aspects must be carried out in some way through the process of a moral evaluation in the context of the patent system.

The controversy regarding the role of patents in research and development of biotechnology products, together with the impact that they may have on this activity, seems to suggest that patent law may represent the 'competent court' for the debate on biotechnology.

However, to limit the debate to patent rights may be misguided. On one hand, the 'moral issue' on the matter essentially concerns the act of technological development, and as such its analysis within the patent system is problematic, given that the patent right concerns the protection of technology once it exists, therefore 'applied research'<sup>121</sup> and not 'pure research'.<sup>122</sup> On the other hand, however, the opposition to a patent on moral grounds obviously amounts in essence to preventing the activity altogether, through withdrawal of the incentive; this indicates that the patent right is a highly significant component of the discipline, at least directly, of biotechnological development.

In any case, there seems to be little evidence to indicate that the 'moral' provisions of patent law are meant to regulate the matter in and of itself. These provisions, first of all, do not have a *de iure* legal basis. Secondly, it is not clear from case law that a *de facto* regulatory approach exists. Rather, moral considerations are mostly applied in order to highlight concerns regarding the determination of that which is or is not socially acceptable, and as such must be faced.

Patent law traditionally remained far from moral arguments, especially in the United States. In Europe, however, moral profiles entered the patent 'ring' directly upon the creation of art. 53 of the European Patent Convention. Essentially inactive until the advent of biotechnology, the rule provides, among other things, that patents not be granted for inventions whose use would be contrary to public order or morality. In this way, issues were entered into the patent system which, until the development of biotechnology, were not considered particularly relevant to it. Thus, today, in the European framework, patent law is an area in which moral issues take on greater importance.<sup>123</sup>

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<sup>121</sup> That is, aimed at the development of industrial applications.

<sup>122</sup> Freed from practical aims, and in any case results. In this regard, in addition to referencing that which will be said in the following Chapters, see in particular, G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 37 et seq.

<sup>123</sup> In argument, see L. Bently and B. Sherman, 'The Question of Patenting Life', in L. Bently and S. Maniatis (eds), *Intellectual Property and Ethics*

The main aim of the patent system, as is stated both in the U.S. and European systems, is to encourage investment and innovation through the protection of inventions.

There is no doubt that economic policy is fundamental to patent law, which contributes to the economic regulation of the market, through the attribution of 'monopoly islands' in a 'sea of competition', which ultimately stimulates the attribution of these temporary monopolies, favoring innovation, investment and therefore exchange.<sup>124</sup>

Conversely, the aim of 'moral policy', if one can be identified, does not appear to be reached adequately through patent law.<sup>125</sup> The doubt which is raised, then, is if patent, designed to pursue mainly economic interests, may effectively intervene to protect moral claims.<sup>126</sup>

A policy which protects moral values may suggest the adoption of excessively limited behaviour with respect to patentability. Thus, it is necessary first to understand what the aims of a moral policy are. Once these have been identified, it is necessary to determine what is the relative 'specific weight' that the economic and moral profiles may have on the patent discipline. At this point, the issue may be brought up as to whether and perhaps in what way it may be possible to achieve the purpose of each policy through their incorporation into patent law.

In this sense, on the one hand, the basic concept of the instances of the participants in the debate, particularly scientists, economists and lawyers,

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(*Perspectives on Intellectual Property, vol. IV*), London: Sweet & Maxwell, 1998, p. 109 et seq.

<sup>124</sup> On this point, see S. Anderman and A. Ezrachi (eds), *Intellectual Property and Competition Law – New Frontiers*, cit., p. 1 et seq.; Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 209 et seq.

<sup>125</sup> See G. Laurie, 'Biotechnology: Facing the Problems of Patent Law, in H.L. McQueen (ed.), *Innovation, Incentive and Reward*', cit., p. 61.

<sup>126</sup> In this sense, for instance, it has been stated that when patentability of biotechnological inventions is discussed under an ethical profile, one must ask about the ethical compatibility of the exclusive regime, as that of professional production – and only this. This implies that biotechnological innovation one is dealing with has already gone beyond the ethical range of applied research, experimentation, professional and business methods of production of goods and services. In short: the issue of patentability of biotechnology under an ethical profile is translated, with remains, into that of ethical compatibility of business production of biotechnological inventions in a regime of exclusivity. Thus, innovation ethics should not be confused with patent ethics (see P. Spada, *Liceità dell'invenzione brevettabile ed esorcismo dell'innovazione*, in *Rivista di diritto privato*, 2000, p. 6 et seq.).

is that a strong patent system is an essential prerequisite for economic development.

The reasoning of the main economic issue is that according to which it is correct to reward the inventor for the time, ability and effort he has put into the creation of an invention. The inventor must be given the possibility to recover her/his investment, without being forced by competitors to lower the price, and therefore never finding her/himself in a position to recover the money invested. On the basis of this argument, exclusivity is justified due to the fact that it is a necessary element to stimulate research and development.

Another argument made in order to justify the patent system is that in which patents help to stimulate innovation and industrial development through the dissemination of technical knowledge. The patent system, operating on the basis of the principle of disclosure, ensures that the details of the invention are made available to the public. Researchers are then free to build upon this knowledge, and in such a way to further contribute to the advancement of technological progress. This argument works also inversely. If technology is excluded from patentability, there is no incentive to invest in research. In a similar situation, collectivity may be denied the knowledge and advantages that a particular technology may offer.

On the other hand, not all accept the assumption that patents have a positive effect, and it is shown how it is not clear up to what point research and development may be damaged following the withdrawal of incentive. In the first place, the patent does not protect the inventor who first has the idea for the invention.<sup>127</sup> It is the first one to present the application for the patent, rather than the first who invents it, who is given priority.<sup>128</sup> Moreover, it is held that from the moment in which the inventions are ready to be developed the industries which have financed them up to that point would inevitably proceed to their development, therefore there is no need to create artificial incentives.<sup>129</sup> Further, in the field of biotechnological innovation, legal systems now require lengthy experimentation of new products, due to which the period of protection

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<sup>127</sup> See W.R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, London: Sweet & Maxwell, 1999 (4th edn), p. 79.

<sup>128</sup> The United States traditionally operated on a 'first to invent' system; the Patent Reform Act 2009, however, introduced a 'first to file' system similar to that of the EPC.

<sup>129</sup> As such, W.R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, cit., p. 80.

on the market is reduced.<sup>130</sup> For these reasons, some doubt the effective role of the patent system on encouraging the use of inventions. This regards in particular, considering their peculiarity, biotechnological inventions.

In addition, the granting of patents is opposed by many outside the system,<sup>131</sup> on the more fundamental basis of traditional arguments; this is, in particular, the reason why, contrary to the past, today the issue of the role of moral evaluations is a debated theme in patent law.

Those opposed to inventions obtained through genetic engineering hold that the recognition of exclusive rights to use such an invention is simply inappropriate. The consideration at the basis of this position is that according to which intellectual property rights may not and should not take precedence over the fundamental rights of man, such as the rights of autonomy, human dignity and the right to live a full and productive life.<sup>132</sup> In this view, the patent system would put in jeopardy especially the rights for personal identity, the development of the individual, food and health.

Moreover, those opposed to the patent system argue that the high level of protection provided by existing national and international regimes moves the delicate balance between public and private in favour of private interests, resulting in a sort of 'marketing of life'.<sup>133</sup>

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<sup>130</sup> For instance, in the pharmaceutical industry often clinical trials prior to the release of a product on the market last 11 or 12 years, as a result, reducing their period of protection. On the importance of patent incentive to encourage innovation in the pharmaceutical and biotechnology sectors, see among others, J.D. Wright, 'Implications of Recent Patent Law Changes on Biotechnology Research and Biotechnology Industry' (1997) 1 *Virginia Journal of Law and Technology* 1 et seq.

<sup>131</sup> Such as religious movements or organizations such as Greenpeace or Friends of the Earth.

<sup>132</sup> With reference to the relation between the discipline of biotechnology and human rights, see among others, C. Kuppaswamy, *The International Legal Governance of the Human Genome*, cit.; B.R. Schaller, *Understanding Bioethics and the Law. The Promise and Perils of the Brave New World of Biotechnology*, Westport (USA)/London: Praeger, 2008; F. Francioni (ed.), *Biotechnologies and International Human Rights*, Oxford/Portland (USA), Hart Publishing, 2007; F. Francioni and T. Scovazzi (eds), *Biotechnologies and International Law*, cit., *passim*.

<sup>133</sup> See A. Oyewunmi, 'The Right to Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma', in J. Gibson (ed.), *Patenting Lives: Life Patents, Culture and Development*, Farnham (UK)/Burlington (USA): Ashgate Publishing, 2008, p. 53 et seq.; F. Vandebaele, *Patentability of Living Organisms: Legal and Ethical Aspects of the Question*,

Biotechnological patents encounter opposition also on the basis of the opinion according to which allowing the patentability of a new human or animal trait is equated with 'condoning' the marketing of life, which would be morally unacceptable.<sup>134</sup> In this sense, the Humane Society of America defined genetic engineering as 'a step backwards in the evolving recognition of the significance of animal life, the sanctity of being and the interconnectedness of all life'.<sup>135</sup>

The position is rooted in the concepts of property and possession, and inappropriateness of the application of them, in particular, over human DNA; while there are not strong objections, for instance, regarding the possession of steers by a breeder and the possibility he has in selling or butchering them. The argument is based on the consideration of the existence of a 'slippery slope': once patents have been granted for animals, it would only be a matter of time before they were granted for humans. In particular, the argument assumes that it is impossible to make a distinction of principle between human and animal life, and that the patentability of animals would lead to the consideration of human life as a commodity, over which patents may be granted.

On the other hand, assumptions made on the basis of such an argument are not fully convincing. The assumption that patentability of animals leads to similar treatment of human life and patentability of it, with a sort of process of 'downgrading' of humans, could be seen on the contrary as a process of 'upgrading' for animals. While the worries related to marketing of life undoubtedly need to be faced, the issue is not resolvable with the aforementioned *a priori* comparison. Rather, it should be entrusted to the appropriate evaluation of specialized authorities in charge of such activities.

In this sense, a particularly relevant profile concerns the risk of the so-called 'tragedy of anticommons', which may result from the sum of patentability of essential information for biotechnological research and inadequate practices of licensing for the relative patents. A situation such as this would create significant obstacles for the work of researchers,

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Montreal: McGill University, 2005, p. 69 et seq.; J. Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World*, New York: J.P. Tarcher/Putnam, 1998, p. 37 et seq.

<sup>134</sup> See, among others: Y. Joly, 'Genetic Research Tools: Recent Trends and Future Outlook', in E.R. Gold and B.M. Knoppers (eds), *Biotechnology IP & Ethics*, Markham, Canada: LexisNexis, 2009, p. 39 et seq. (47 et seq.); D.B. Resnik, *The Morality of Human Gene Patents*, cit., p. 54 et seq.

<sup>135</sup> In this regard, see M. Paver, 'All Animals Are Patentable, But Some Are More Patentable Than Others' (1992) 9 *Patent World* 9 et seq.

who would be discouraged by the prohibitive costs of obtaining the necessary licences to use a product or process fundamentally necessary for the development of their research.<sup>136</sup>

In any case, it appears clear that patent law is characterized mainly as a tool for economic policy. It provides an incentive to invest and innovate. What is more, through the tool of disclosure, it provides a centralized system of information gathering in order for other inventors to gather ideas or develop new inventions.

On this basis, supporters of patentability of living organisms argue that a mechanism of incentive is essential to guarantee the production of benefits resulting from biotechnological research, including in particular those for health treatment, agriculture and environmental protection.

The arguments against biotechnology in and of itself, again, state that the creation itself of relative inventions is problematic. The key objection appears to be that biotechnology, and in particular genetic engineering, is conceptually wrong in and of itself, even where benefits outweigh the damage caused. The reasons are essentially the following: (a) biotechnology is an attempt to 'play God';<sup>137</sup> (b) genes represent a 'common patrimony of humanity', 'common interest of humanity', or 'public asset',<sup>138</sup> and, according to a more radical formulation, should be passed on from generation to generation without human intervention; and (c) genes naturally exist in organisms and should not be interfered

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<sup>136</sup> In this regard see, *ex multis*, M. Heller, 'The Tragedy of Anticommons' (1998) 111 *Harvard Law Review* 621 et seq.; M. Heller and R.S. Eisenberg, 'Can Patent Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698 et seq.; G. Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, cit., p. 37 et seq.; R. Gold and B.M. Knoppers, *Biotechnology IP & Ethics*, cit., p. 52. For further consideration on the theme, refer to Parts III and V.

<sup>137</sup> See, among others, M. Bratton (ed.), *God, Ethics & the Human Genome*, London: Church House Publishing, 2009, *passim*; J. Boyle, 'Enclosing the Genome: What Squabbles Over Genetic Patents Could Teach Us', in F. Scott Kieff (ed.), *Perspective on Properties of the Human Genome Project*, San Diego: Elsevier Academic Press, 2003, p. 97 et seq.; J. Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World*, cit., p. 60 et seq.; M.J. Hanson, 'Religious Voices in Biotechnology. The Case of Gene Patenting' (1997) 27 *Hastings Center Law Report* 1 et seq.

<sup>138</sup> See, *ex multis*, R. Gold and B.M. Knoppers, *Biotechnology IP & Ethics*, cit., p. 47 et seq. (as well as the numerous references cited herein); B.M. Knoppers and Y. Joly, 'Our Social Genome?' (2007) 25 *Trends in Biotechnology* 284 et seq.

with.<sup>139</sup> The argument following such considerations is that which states that it does not consider how much men progress in biotechnology, because they should simply not be using it at all.

Those opposed to this argument reveal that this approach appears in reality to take a position, rather than justify it. Considering that any interference in natural processes may be described as 'playing God', it is stated that the mere fact that genetic engineering allows for control over life is not an acceptable moral objection. Unless the control used by human beings over nature in virtue of genetic engineering can be distinguished from the control they exercise routinely over nature in other ways, genetic engineering should be considered morally equivalent to the other human intrusions on nature; among these, clearly, are the actions which benefit life, for instance, the use of medicines (also obtained thanks to genetic engineering).<sup>140</sup>

With regard to human interest, then, in reality it seems to be served through the incentive to scientific and technological research which allows benefits to be obtained from inventions resulting from it, without it inhibiting the establishment, where appropriate, of any limits of patentability.<sup>141</sup>

What is more, the fact that genetic engineering is a risky practice, the consequences of which are widely unknown, is not held to be a legitimate moral argument against biotechnology. For new technology, in the first stages of development, the actual results are unknown. The problem of security is not exclusive to the sector of genetic engineering, but must be faced with specific reference to the given context.<sup>142</sup>

On the other hand, it should be noted that there is a moral, as well as legal, obligation of individuals to be responsible for the benefits granted them by legislature. In this view, aside from the consideration according to which the patent system is not the appropriate place to evaluate moral

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<sup>139</sup> See S. Sterckx, 'European Patent Law and Biotechnological Inventions', in S. Sterckx (ed.), *Biotechnology, Patents and Morality*, Farnham (UK)/Burlington (USA): Ashgate Publishing, 1997, p. 1 et seq.

<sup>140</sup> On this point, see F. Vandenabeele, *Patentability of Living Organisms: Legal and Ethical Aspects of the Question*, cit., p. 68; B. Hoffmaster, 'The Ethics of Patenting Higher Life Forms' (1988) 4 *Intellectual Property Journal* 1 et seq. (especially p. 4).

<sup>141</sup> See World Health Organization, 'Genetics, genomics and the patenting of DNA. Review of potential implications for health in developing countries', Geneva, 2005, accessed 12 December 2014 at <http://www.who.int/genomics/FullReport.pdf>, p. 31 et seq.

<sup>142</sup> According to B. Hoffmaster, 'The Ethics of Patenting Higher Life Forms', cit., p. 1 et seq.

profiles, it is frequently used explicitly to exclude certain inventions from patentability, in virtue, in fact, of moral considerations. Patent regimes have often functioned as 'moral filters', allowing a certain form of innovation to enter the market and blocking others.<sup>143</sup> The limitations to patentability have allowed the courts and patent offices to pass value judgments on the issue of social interest.<sup>144</sup>

A further argument on the moral order of things against biotechnology is in regard, then, to the experimentation on animals for purposes of genetic engineering, which is held to be unacceptable given that it inflicts pain and suffering on animals for aims which in comparison appear to be of minor importance.<sup>145</sup> The difficulty in sustaining such an argument lies in its being based on the absolutist approach which highlights only one value, that of protecting animals. A discipline which takes morals into account requires a continuous balancing of conflicting values.<sup>146</sup>

Further, the difficulty in identifying the difference between genetic engineering and other technology has been shown to be such that many moral questions have arisen in regard to the former. This, even more in virtue of the fact that also in Europe the European Patent Office, like the U.S. Patent Office, in consenting to the patentability of life forms, has apparently reconciled science and profit. The essential point concerns the examination of whether a higher moral standard can be justified on the basis of the consideration for which biotechnology deals with life, and the negative consequences of it which could be catastrophic. At most, every science, including genetic engineering, may demonstrate advantages and disadvantages at a moral level. The issue, then, is that of identifying where the line should be drawn, which consequence society will see as a tolerable evil produced by genetic engineering.

In the context of the patent system, then, the function of morality appears to identify relevant issues for the determination of what is and is

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<sup>143</sup> See A.J. Wells, 'Patenting New Life Forms: An Ecological Perspective' (1994) 3 *European Intellectual Property Review* 111 et seq.

<sup>144</sup> Think, for instance, of the case of prohibition of patentability of nuclear weapon technology in the United States (42 USC s.218(a) 1982).

<sup>145</sup> In this regard, see again B. Hoffmaster, *The Ethics of Patenting Higher Life Forms*, cit., p. 8.

<sup>146</sup> See R. Ford, 'The Morality of Biotech Patents: Differing Legal Obligations in Europe?' (1997) 6 *European Intellectual Property Review* 315 et seq.

not acceptable for society. At this point, specialized authorities responsible for this issue can, through adequate regulations, exercise the relative control.<sup>147</sup>

In this sense, with particular reference to microorganisms, the worry is that modified organisms may spread in the environment escaping from the lab where they were produced, without scientists knowing what effects they may have on future generations.

With regard to plants, the worry is substantially the same, or rather that modified plants may spread in the environment, with related risks for ecological balance.<sup>148</sup> Those in opposition to genetic engineering, on the other hand, are not convinced by the consideration according to which, once it has been established that modified plants are not damaging, there are not negative effects for the environment. In the case of plants, then, there is a further objection, which is that genetic modification will give rise to a reduction in biological diversity, or biodiversity, a concept that indicates the variability of living organisms of every type, including those on land, in the sea and ecological complexes and water ecosystems of which they are a part.<sup>149</sup> In this regard, on the one hand, it is stated that in the long term only plants useful for the interest of man will remain and biodiversity will be reduced in an unacceptable way. On the other hand, it is affirmed, however, that biodiversity may be enriched by the introduction of external genes (from non-plants or other plants) to existing plants.

As far as animals are concerned, in the first place, arguments against genetic modification are similar to those raised for plants. The concern, also in this case, is regarding the danger of destroying the ecosystem due

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<sup>147</sup> See O. Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, cit., p. 15 et seq.

<sup>148</sup> Though biotechnology has been relatively successful in transforming plants for agriculture, concerns remain for profiles of security and sustainability. What is more, the more recent engineering techniques of precision seem able to relieve also some of the concerns regarding biosecurity. In this regard, see C.N. Stewart and D.W. Ow, 'The Future of Plant Biotechnology', in C.N. Stewart (ed.), *Plant Biotechnology and Genetics: Principles, Techniques, and Applications*, New York: Wiley & Sons, 2008, p. 357 et seq.

<sup>149</sup> Biodiversity detected within species, between species and ecosystems. On this theme, see the Convention on Biological Diversity, opened and signed in Rio de Janeiro on 5 June, 1992 and implemented on 29 December, 1993, art. 2. In doctrine, regarding the role of patents in order to achieve the objective of the Convention, see C. Lawson, 'Patents and Biological Diversity Conservation, Destruction and Decline? Exploiting Genetic Resources in Queensland under the Biodiscovery Act 2004' (2006) 28 *European Intellectual Property Review* 418 et seq.

to the release of transgenic animals into the environment. The argument of the reduction of biodiversity, then, is invoked also in relation to animals, stating that only those useful to man would remain. On one hand, the statement is reinforced by the observation according to which the characteristics of animals are modified in a way that will benefit man, but rarely the animals themselves. On the other, the objection is that also in this case biodiversity may be enriched as a result of the introduction of foreign genes (of non-animals or other animals) into existing animals.

Once again, in consideration of the fact that the animals are considered to fall under the category of higher forms of life (with humans), a further objection concerns the methods and consequences of experimentation on animals. In particular, it is asked whether these experiments are necessary, if it is acceptable to carry them out on animals for different purposes other than their health and well-being, and if and in which case the use of animals as bio-reactors should be allowed.

Beyond these questions, the fundamental theme appears to be that of evaluation of whether the damage done to animals takes precedence or not over the benefit to human beings.<sup>150</sup> In addition, the main doubts regard the negative impact that transgenic animals may have on their own species. The concern is based on the assumption that the transfer of genes between species crosses the natural barriers existing between them, violating their integrity.<sup>151</sup>

In any case, evidently the more complex situations presented by biotechnology arise when considering genetic modification of human beings. The threat posed by today's biotechnology lies in the possibility that they may alter human nature in an immoral and perhaps unrecoverable way.

The main moral issues raised by the application of biotechnology to human life concern, in particular,<sup>152</sup> the doubts regarding the possibility

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<sup>150</sup> See G. Annas, 'Of Monkeys, Man and Oysters' (1987) 17 *Hastings Center Report* 20 et seq.

<sup>151</sup> With regard to arguments for and against the patentability of animals, see U.S. Congress – Office of Technology Assessment, 'New Developments in Biotechnology: Patenting Life – Special Report', OTA-BA-370, Washington DC, U.S. Government Printing Office, April 1989, accessed 12 December 2014 at [ota-cdn.fas.org/ota/reports/8924.pdf](http://ota-cdn.fas.org/ota/reports/8924.pdf).

<sup>152</sup> In this regard, besides what will be said more extensively below, see among others, E. Arezzo and G. Ghidini, *Biotechnology and Software Patent Law: A Comparative Review of New Developments*, cit., especially p. 221 et seq.; D.R. Koepsell, *Who Owns You? The Corporate Gold-Rush to Patent Your Genes*, cit.; D. Magnus, A.L. Caplan and G. McGee (eds), *Who Owns Life?*, cit., *passim*; Gold and Knoppers, *Biotechnology IP & Ethics*, cit., *passim*; Bratton, *God Ethics*

for humans to possess their own genetic material, held by many as being common property of humanity and as such belonging to society as a whole; the risks of violation of human dignity which interventions on the human genome may involve; the criticism of genetic therapy, or rather the production of healthy couples of defective genes, as a tool which may surpass the morally acceptable limits of human intervention on life; and the condemnation of practices furthest from the moral standards of our society, such as human cloning or eugenics.

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*& the Human Genome*, cit., *passim*; B. Looney, 'Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement' (1994) 26 *Law and Policy in International Business* 231 et seq.